

**EPA REGISTRATION NUMBER 40810-25 – VOL. 1**

SUBMISSION BAR CODE # 8635944 REVIEWER T Kish

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 40810-EL <sup>(25)</sup> PM 33 ACTION CODE 173

DESCRIPTOR Revised Labeling

[ ] CHILD RESISTANT PACKAGING: [ ] CERTIFICATION  
[ ] NON-RESIDENTIAL USE ONLY  
[ ] NOT APPLICABLE

REGISTRATION TYPE: [ ] CONDITIONAL [ ] UNCONDITIONAL

PROPOSED CLASSIFICATION: [ ] GENERAL [ ] RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

05 15 03

05 15 03

15 19 03

~~METHOD OF SUPPORT~~

~~FORMULATORS EXEMPTION~~

[ ] ~~CITE ALL~~  
[ ] ~~SELECTIVE~~  
[ ] ~~NOT SUBMITTED~~  
[ ] ~~NOT APPLICABLE~~  
[ ] ~~INCORRECT/RESUB~~

[ ] ~~SUBMITTED~~  
[ ] ~~NOT SUBMITTED~~  
[ ] ~~NOT APPLICABLE~~  
[ ] ~~INCORRECT/RESUB~~

REVIEW(S) REQUESTED

DATA  
PACK #

DATE  
SENT

DUE  
DATE

DATE  
RETURNED

CHEMISTRY

EFFICACY

TOXICOLOGY

HED TOX.

ENVIRON. FATE

FISH/WILDLIFE

OTHER


STATUS

JUL 30 2003

RESPONSE CODE 18

JUL 30 2003

RESPONSE DATE





U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Antimicrobials Division (7510C)  
1200 Pennsylvania Avenue, N.W.  
Washington, D.C. 20460

EPA Reg.  
Number:

40810-25

Date of Issuance:

JUL 30 2003

NOTICE OF PESTICIDE:

  X   Registration  
       Re-registration

Term of Issuance:  
CONDITIONAL

Name of Pesticide Product:

"IRGAGUARD B102Z"

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP code):

Ciba Specialty Chemicals Corporation  
540 White Plains Road  
P.O. Box 2005  
Tarrytown, NY 10591-9005

**Note:** Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA Section 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA Section 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA Section 4.

2. Submit three final printed labels within 90 days of this letter which make the following change:

a. Revise the EPA Registration Number to read,  
"EPA Reg. No. 40810-25".

Signature of Approving Official:

Marshall Swindell,  
Product Manager, Team 33,  
Regulatory Management Branch I,  
Antimicrobials Division

Date:

JUL 30 2003



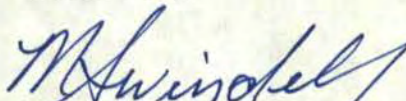
page 2  
EPA Reg. No. 40810-25

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA Section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the accepted label is enclosed for your records.

If you have any questions concerning this letter, please contact myself at 703-308-6341, or Tony Kish at (703) 308-9443.

Sincerely,

A handwritten signature in blue ink, appearing to read "M. Swindell", is written over the typed name.

Marshall Swindell  
Product Manager 33  
Regulatory Management Branch 1  
Antimicrobial Division (7510C)

Enclosure



# IRGAGUARD® B102 Z

Zinc zeolite

An antimicrobial agent for formulating use only.

Active ingredient:  
Zinc (as elemental) ..... 14.3%  
Other ingredients..... 85.7%  
Total..... 100.0%

**KEEP OUT OF REACH OF CHILDREN**

## CAUTION

### FIRST AID:

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

#### IF IN EYES

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye
- Call a poison control center or doctor for treatment advice

**FOR 24-HOUR EMERGENCY MEDICAL ASSISTANCE, CALL  
1-800-873-1138**

EPA Establishment No. 70404-AL-002

EPA Registration No. 40810-

Net Weight

Lot No.

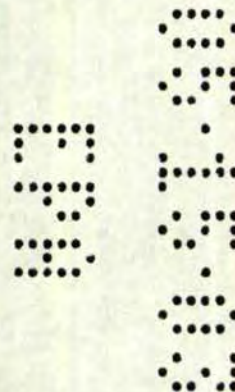
Ciba Specialty Chemicals Corp.  
Plastic Additives  
540 White Plains Road  
Tarrytown, NY 10591

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

**JUL 30 2003**

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No.

**40810-25**





## PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMANS

**CAUTION.** Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Only for formulation into antimicrobial pesticides, for (1) use as Materials Preservatives in adhesives, sealants, caulks, coatings, films, laminates, plastics (including films, sheets, slabs, and molded plastic parts), fibers (for apparel, interior furnishings, industrial and other household items, packaging, transportation items), specialty products (cat litter, drainage and sewage pipe, flooring, plaster, sinks, stucco, tile, toilets); (2) uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and (3) uses for experimental purposes that are in compliance with USEPA requirements.

Formulators using this product are responsible for providing data for the EPA registration of their formulated products.

### ENVIRONMENTAL HAZARDS

This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

**Pesticide Storage:** Do not store in areas accessible to children. Keep away from direct sunlight.

**Pesticide Disposal:** Wastes from the use of this product may be disposed of on site or at an approved waste disposal facility.

**Container Disposal:** Completely empty bags into processing equipment where the pesticide is used. Then dispose of empty bag and box in sanitary landfill or by incineration, if allowed by state and local authorities.

**IRGAGUARD® is a trademark of Ciba Specialty Chemicals Corporation**

EPA Approval Date: NOT EPA APPROVED. Draft 05-08-2003

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

JUL 30 2003

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No.

40810-25





# ChemReg

INTERNATIONAL, LLC

1990 OLD BRIDGE ROAD, SUITE 201  
LAKE RIDGE, VIRGINIA 22192-2383

DIRECT: 703-492-7905  
MAIN: 703-492-0445  
Fax: 703-492-0668

E-MAIL: brown@chemreg.com  
WEB SITES: www.chemreg.com  
www.pesticide.net

**ELIZABETH A. BROWN, PH.D.**

May 15, 2003

Document Processing Desk  
Office of Pesticide Programs (7504C)  
U.S. Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202-4501

Attention: Marshall Swindell (PM 33)

Re: Irgaguard B 102 Z, (EPA File Symbol 40810-EL)  
Agency Letter of April 17, 2003 plus subsequent communications

Dear Marshall:

On behalf of our client, Ciba Specialty Chemicals Corporation, this is a resubmission in response to the Agency letter of April 17, 2003, based on subsequent clarifications by phone and email. We want to reiterate that this product is a manufacturing-use product, intended only for formulation into another registered pesticide (registration pending under EPA File Symbol 40810-ET).

Labeling: In accordance with the Agency letter and subsequent phone conversation on April 29, 2003, the draft labeling has been revised as directed and agreed. Five copies of the draft labeling are enclosed. The precautionary wording has been revised in accordance with that on the label for the product cited for acute toxicity, PR 2001-1 and 66 FR 64759-68. As previously agreed with you, item 3 under Labeling Changes in the Agency letter of 4/17/03 is not pertinent to this product.

Data Compensation: In accordance with the Agency letter and subsequent communications, the data matrix has been revised to address the items required in the Agency letter. We note that the Agency agreed that data from the zinc RED was acceptable to fulfill generic data requirements. A revised certification with respect to citation of data is enclosed, as required.

---

**CONSULTANTS TO SUCCESS<sup>SM</sup>**

Over One Hundred and Fifty Years of Combined Experience Assisting Chemical, Pesticide, Bio-Chemical and Life Science Companies on a Wide Range of Issues, Including Regulatory Strategies, Registration, Data Support and Compensation, Quality Assurance, Study Design and Scientific Matters.



# ChemReg

INTERNATIONAL, LLC

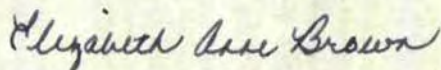
Letter to M. Swindell, May 15, 2003, page 2

In response to the Agency letter of April 17, 2003, Point 2 under Product Chemistry: A revised CSF is enclosed, based on the specific direction given by Tony Kish on May 15, 2003. We are reiterating that the Chemistry review for this product (Dated 12/19/2002 under DP Barcode D287262) is incorrect. That review states that this product is made by a non-integrated system. As clearly described in the supporting MRIDs (457770-01 and -02), this product is manufactured by an integrated system. Further, as discussed with the Agency on May 9, 13, and 15, the changes required by the Agency for this product were inconsistent with prior Agency direction and acceptance on essentially identical products also made by integrated systems. However, we have made the changes per Tony Kish's direction.

We thank the Agency for its recent clarification of requirements for this application and believe we have addressed all items as the Agency has required. We wish to point out that the Agency previously has given differing and inconsistent direction regarding the requirements for registration of this type of product and specifically on this application for registration. We therefore respectfully request an expedited review of this qualifying resubmission.

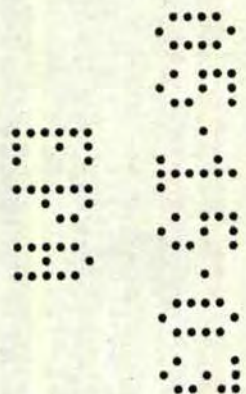
Please let me know immediately if there are any questions.

Regards,




Elizabeth Anne Brown

cc: Ciba Specialty Chemicals Corporation





 <b>United States</b> <b>Environmental Protection Agency</b> Washington, DC 20460	<input type="checkbox"/> <b>Registration</b>	OPP Identifier Number
	<input type="checkbox"/> <b>Amendment</b>	
	<input checked="" type="checkbox"/> <b>Other</b>	

**Application for Pesticide – Section I**

1. Company/Product Number 40810-EL	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Irgaguard B 102 Z	PM # 33	
5. Name and Address of Applicant (Include ZIP Code) Ciba Specialty Chemicals Corporation 540 White Plains Road PO Box 2005 Tarrytown, New York 10591-9005 <input type="checkbox"/> Check if this is a new address		6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg No. _____ Product Name _____

**Section - II**

<input type="checkbox"/> Amendment – Explain below  <input checked="" type="checkbox"/> Resubmission in response to Agency letter dated <u>4/17/2003</u>  <input type="checkbox"/> Notification – Explain below	<input type="checkbox"/> Final printed labels in response to Agency letter dated <input type="checkbox"/> "Me Too" Application  <input type="checkbox"/> Other – Explain below
---	---

**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)

Resubmission in response to Agency letter of 4/17/03 and phone call of 4/29/2003

**Section III**

1. Material This Product Will be Packaged in:						2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
<b>*Certification must be submitted</b>		If "Yes" Unit Packaging wgt.		No. per container		If "Yes" Package wgt.	
						No. per container	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container				4. Size(s) Retail Container		5. Location of label directions <input type="checkbox"/> On Label <input type="checkbox"/> On Label accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____							

**Section IV**

1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Elizabeth Anne Brown		Title ChemReg International, LLC Authorized Agent	
		Telephone No. (Include Area Code) 703-492-7905	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law			6. Date Application Received 
2. Signature 		3. Title ChemReg International, LLC Authorized Agent	
4. Typed Name Elizabeth Anne Brown		5. Date 5/15/2003	





Elizabeth Brown  
<brown@chemreg.co  
m>

07/23/03 03:03 PM

To: Tony Kish/DC/USEPA/US@EPA, Marshall  
Swindell/DC/USEPA/US@EPA

cc:

Subject: confirming phone calls re 40810-EL

Tony and Marshall:

I just want to reconfirm phone calls today regarding the acute toxicity support for Irgaguard B102Z (EPA File Symbol 40810-EL), particularly Tony's concerns about whether it should be tox category III or IV for dermal toxicity.

Our proposed labeling for this MUP product, which contains 14.3% zinc, is based on citing data submitted in support of EPA Reg. No. 71645-3 (99% zinc oxide). EPA Reg. No. 71645-3, based on the Oct 21, 2002 EPA approved label on PPLS, is tox category IV for all but eye irritation, which is tox category III. That is consistent with what we have proposed for 40810-EL; we specifically cited MRIDs supporting that registration for the product-specific acute toxicity data (see data matrix citations with reference to footnote 11).

Further, the zinc RED states that zinc oxide dermal toxicity is > 5000 mg/kg bw, which should mean it is tox category IV for dermal toxicity, even though the RED (incorrectly) indicates the tox category is III for that result.

In summary, we believe that the cited data are appropriate to support the hazard classification of 40810-EL and that the product is tox category IV for all except eye irritation, which is tox category III.

The product-specific acute toxicity of the other pending applications from Ciba are based on other data, as cited within the specific application for each. However, all are consistent in hazard classification, with all being tox category IV for all routes except eye irritation, which is tox category III.

I will look forward to hearing back from you very soon regarding your conclusions.

Regards,  
Elizabeth

*Elizabeth Anne Brown, Ph.D.*  
*ChemReg International*  
*1990 Old Bridge Road, Suite 201*  
*Lake Ridge, VA 22192*

Phone: 703-492-7905  
Fax: 703-492-0668  
Email: brown@chemreg.com



## Bibliography

## MRID

## Citation Reference

43258601 Hoffman, G. (1994) An Acute (4-Hour) Inhalation Toxicity Study of Zinc Oxide in the Rat via Nose-only Exposure: Final Report: Lab Project Number: 93-5171: BD-94-6. Unpublished study prepared by Pharmaco LSR Inc. 57 p.

*all 6 <sup>cited</sup> acutes to support 71645-3 (label show tox 3 only for eye. Citing these acutes used for 71645-3 is accurate to satisfy prod specific acutes for 40810-EL because they also result in a tox 3 category only for eye. Red listing for zinc oxide as tox 3 for dermal @ >5000 should be tox 4 also.*



# ZINC OXIDE

Antimicrobial Agent

## ACTIVE INGREDIENT:

Zinc Oxide ..... 99.4%

OTHER INGREDIENTS ..... 0.6%

Total 100.0%

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

See additional precautionary information elsewhere on label.

EPA Reg. No. 71645-3

EPA Est. No. 71645-AL-1

NET 50 LB.

08/2002

## PRECAUTIONARY STATEMENTS

### Hazards to Humans and Domestic Animals

## CAUTION!

CAUSES MODERATE EYE IRRITATION

Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.

### First Aid

Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

Call a poison control center or doctor for treatment advice. Have the product container with you when calling a poison control center or doctor, or going for treatment. You may also contact CHEMTREC (800-424-9300) for emergency treatment information.

### Environmental Hazard

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

The purpose of adding ZII adverse moisture conditioning bacteria in areas where would potentially result in odors.

It is a violation of Federal law.

For Manufacturing use only. For incorporation into nylon fungistatic agent. The resin in the nylon fiber.

For use, add prescribed amount after polymerization to obtain.

STORAGE: Store in a dry, do not contaminate water.

PESTICIDE DISPOSAL: Wipe on site or at an approved CONTAINER DISPOSAL. E safeguards until container dispose of empty bag in a local authorities, by burning.

Manufactured for Solutia Inc., St. Louis, Missouri 63141 U.S.A. Tel. (314) 674-1000

**ACCEPTED**

OCT 21 2002

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 71645-3



**Wallace Powell**

07/23/03 02:52 PM

To: Tony Kish/DC/USEPA/US@EPA

cc:

Subject: Zinc

See attached



Zinc elemental - Data listed in PDMS.



There's one currently registered TGAI product in REFS: Reg. No. 67771-1. No studies of any kind listed in PDMS for this product.  
Another registered TGAI: 71645-3.

Data listed in PDMS (mainframe) for elemental zinc:

Study	MRID	1 <sup>st</sup> submitted for (Reg. No.) or by	Data 1 <sup>st</sup> submitted
Acute oral toxicity	45618304	40810-18	02/26/2002
Acute dermal toxicity	45618305	40810-18	02/26/2002
Acute inhalation tox.	45618306	40810-18	02/26/2002
Eye irritation	45618307	40810-18	02/26/2002
Skin irritation	45618308	40810-18	02/26/2002
Acute oral toxicity	45618604	40810-19	02/27/2002
Acute dermal toxicity	45618605	40810-19	02/27/2002
Acute inhalation tox.	45618606	40810-19	02/27/2002
Eye irritation	45618607	40810-19	02/27/2002
Skin irritation	45618608	40810-19	02/27/2002
Acute inhalation tox.	43617701	Company # 50019	04/18/1995
Eye irritation	43617702	Company # 50019	04/18/1995
Skin irritation	43617703	Company # 50019	04/18/1995





**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M STREET, S.W.**  
**WASHINGTON, D.C. 20460**

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.

Do not send the completed form to this address.

**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number  
 Ciba Specialty Chemicals Corp.  
 540 White Plains Road, P.O. Box 2005  
 Tarrytown, NY 10591-9005, 914-785-4311

EPA Registration Number/File Symbol  
 40810-EL 25

Active Ingredient(s) and/or representative test compound(s)  
 Zinc

Date  
 4/30/03

General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)  
 Indoor Nonfood (material preservative)

Product Name  
 Irgaguard B102Z

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need submit this form. You must submit the Formulators Exemption Statement (EPA Form 8570-27)

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT (Check one method only)**

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose)

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used). **For Product Specific and Generic Data**

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method, or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration or this Data-Call-In response is supported by all data submitted or cited in application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitted to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under applicable law.

Signature

*Naeem Mady*

Date  
 4/30/2003

Typed or Printed Name and Title  
 Naeem Mady  
 Head, Regulatory Affairs





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

**DATA MATRIX**

Date: May 8, 2003	EPA Reg No./ File Symbol 40810-EL	Page 1 of 4
Applicant's/Registrant's Name and Address: Ciba Specialty Chemicals Corporation 540 White Plains Road PO Box 2005 Tarrytown, NY 10591-9005	Product: Irgaguard® B102 Z Manufacturing Use	
Ingredient: zinc (PC 129015)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<b>PRODUCT SPECIFIC DATA</b>					
OPPTS 830.1550	Product Identity and Composition	45777001	Ciba Specialty Chemicals	Own	
OPPTS 830.1600	Description of Starting Materials	45777001	Ciba Specialty Chemicals	Own	
OPPTS 830.1620	Description of the production Process	45777001	Ciba Specialty Chemicals	Own	
OPPTS 830.1670	Discussion of the Formation of Impurities	45777001	Ciba Specialty Chemicals	Own	
OPPTS 830.1700	Preliminary analysis	45777001	Ciba Specialty Chemicals	own	
OPPTS 830.1750	Certified Limits	45777001	Ciba Specialty Chemicals	Own	
OPPTS 830.1800	Enforcement analytical method	45777001	Ciba Specialty Chemicals	Own	
OPPTS 830.6303	Physical state	45777002	Ciba Specialty Chemicals	Own	
OPPTS 830.7000	pH	45777002	Ciba Specialty Chemicals	Own	
OPPTS 830.6314	Oxidation/reduction: chemical incompatibility	Waiver	Ciba Specialty Chemicals	Own	
OPPTS 830.6320	Corrosion characteristics	Waiver	Ciba Specialty Chemicals	Own	
OPPTS 830.6302	Color	45777002	Ciba Specialty Chemicals	Own	
OPPTS 830.6304	Odor	45777002	Ciba Specialty Chemicals	Own	
OPPTS 830.6315	Flammability	Waiver	Ciba Specialty Chemicals	Own	
OPPTS 830.6316	Explosibility	45618603	Ciba Specialty Chemicals	Own	
OPPTS 830.6319	Miscibility	Waiver	Ciba Specialty Chemicals	Own	
OPPTS 830.7100	Viscosity	Waiver	Ciba Specialty Chemicals	Own	
OPPTS 830.7300	Density	45777002	Ciba Specialty Chemicals	Own	
OPPTS 870.1100	Acute oral toxicity – rat	147624	Monsanto	Old	Footnote 11
OPPTS 870.1200	Acute dermal toxicity – rat	147625	Monsanto	Old	Footnote 11
OPPTS 870.1300	Acute inhalation toxicity	43258601	Monsanto	Pay	Footnote 11
OPPTS 870.2400	Primary eye irritation – rabbit	147627	Monsanto	Old	Footnote 11

Signature <i>Naeem Mady</i>	Name and Title Naeem Mady Head, Regulatory Affairs	Date 5/8/03
--------------------------------	--	----------------





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: May 8, 2003	EPA Reg No./ File Symbol 40810-EL	Page 2 of 4
Applicant's/Registrant's Name and Address: Ciba Specialty Chemicals Corporation 540 White Plains Road PO Box 2005 Tarrytown, NY 10591-9005		Product: Irgaguard® B102 Z Manufacturing Use
Ingredient: zinc (PC 129015)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 870.2500	Primary dermal irritation	147626	Monsanto	Old	Footnote 11
OPPTS 870.2600	Dermal sensitization	43258602	Monsanto	pay	Footnote 11
<b>GENERIC DATA - ZINC</b> <i>Per EPA letter of 4/17/03, reference zinc oxide</i>					
830.6302	Color	41777903	Monsanto	Pay	Footnote 11
830.6303	Physical state	41777903	Monsanto	Pay	Footnote 11
830.6304	Odor	41777903	Monsanto	Pay	Footnote 11
830.6313	Stability	41777903	Monsanto	Pay	Footnote 11
830.7000	pH	41777903	Monsanto	Pay	Footnote 11
830.7200	Melting point	41777903	Monsanto	Pay	Footnote 11
830.7220	Boiling point	41777903	Monsanto	Pay	Footnote 11
830.7300	Density/relative density/bulk density	41777903	Monsanto	Pay	Footnote 11
830.7370	Dissociation constant	41777903	Monsanto	Pay	Footnote 11
830.7840-7860	Solubility	41777903	Monsanto	Pay	Footnote 11
830.7950	Vapor pressure	41777903	Monsanto	Pay	Footnote 11
870.1100	Acute oral toxicity - rat	147624	Monsanto	Old	Footnote 11
870.1200	Acute dermal toxicity - rat	147625	Monsanto	Old	Footnote 11
870.1300	Acute inhalation toxicity	43258601	Monsanto	Pay	Footnote 11
870.2400	Primary eye irritation - rabbit	147627	Monsanto	Old	Footnote 11
870.2500	Primary dermal irritation	147626	Monsanto	Old	Footnote 11
870.2600	Dermal sensitization	43258602	Monsanto	pay	Footnote 11

Signature

Name and Title

Naeem Mady  
Head, Regulatory Affairs

Date

5/8/03

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.  
WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: May 8, 2003	EPA Reg No./ File Symbol 40810-EL	Page 3 of 4
Applicant's/Registrant's Name and Address: Ciba Specialty Chemicals Corporation 540 White Plains Road PO Box 2005 Tarrytown, NY 10591-9005		
Product: Irgaguard® B102 Z Manufacturing Use		
Ingredient: zinc (PC 129015)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.3250	90 day dermal toxicity – rodent	RED Ref		Pub	Footnote 5,6,9
870.3700	Developmental toxicity – rodent	RED Ref		Pub	Footnote 7, 9
870.5265	In vitro mutagenicity	RED Ref		Pub	Footnote 7, 9
870.5300	Mutagenicity – mammalian cells in culture	RED Ref		Pub	Footnote 7, 9
870.5380	In vivo cytogenetics	RED Ref		pub	Footnote 7, 9
850.1010	Daphnia acute toxicity	155227	Monsanto	old	
850.1075	Acute toxicity – fish	155224 155228	Monsanto	old	
850.2100	Avian Acute toxicity	155226	Monsanto	old	
835.2120	Hydrolysis	RED Ref		pub	Footnote 8, 9

Footnote 5: Published literature references cited in Zinc Salts RED (US EPA 1992):

- FASEB, 1973. Evaluation of the Health Aspects of certain zinc salts as food ingredients. SCOGS-21

Footnote 6: Published literature references cited in Zinc Salts RED (US EPA 1992):

- NIOSH, 1987. Registry of Toxic Effects of Chemical Substances. Washington, DC

- FASEB, 1973. Evaluation of the Health Aspects of certain zinc salts as food ingredients. SCOGS-21

Footnote 7: Published literature references cited in Zinc Salts RED (US EPA 1992):

- Sax, N. and Lewis, R. 1989. Dangerous Properties of Industrial Materials. 7<sup>th</sup> Ed. Van Nostrand Reinhold, NY

- NIOSH, 1987. Registry of Toxic Effects of Chemical Substances. Washington, DC

Footnote 8: Published literature references cited in Zinc Salts RED (US EPA 1992):

- RED pages 6, 11

- NIOSH, 1987. Registry of Toxic Effects of Chemical Substances. Washington, DC

Signature

Name and Title

Naeem Mady  
Head, Regulatory AffairsDate  
5/8/03

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: May 8, 2003	EPA Reg No./ File Symbol 40810-EL	Page 4 of 4
Applicant's/Registrant's Name and Address: Ciba Specialty Chemicals Corporation 540 White Plains Road PO Box 2005 Tarrytown, NY 10591-9005	Product: Irgaguard® B102 Z Manufacturing Use	
Ingredient: zinc (PC 129015)		

## Footnote 9: Published literature references:

- U.S. DHHS. PHS. Agency for Toxic Substances and Diseases Registry, Dec. 1994. Toxicology Profile for Zinc.
- WHO. 2001. Environmental Health Criteria - Zinc. EHC 221.
- FNB. 2002. Dietary reference intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc. National Academies of Science, Food and Nutrition Board. National Academies Press.

Footnote 11: Cited data are from EPA Reg. No. 524-354 (registration transferred to 71645-3), a 99.4% zinc oxide product and are cited in the RED or fulfilled RED DCI requirements.

503

2003.05.08

Signature

*Naeem Mady*

Name and Title

Naeem Mady  
Head, Regulatory Affairs

Date

5/8/03



SUBMISSION BAR CODE # 8633532 REVIEWER J/C

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 40810-EL PM 33 ACTION CODE 173

DESCRIPTOR EPA letter related to 8633533  
due to TGA discussion internal

[ ] CHILD RESISTANT PACKAGING: [ ] CERTIFICATION  
[ ] NON-RESIDENTIAL USE ONLY  
[ ] NOT APPLICABLE

REGISTRATION TYPE: [ ] CONDITIONAL [ ] UNCONDITIONAL

PROPOSED CLASSIFICATION: [ ] GENERAL [ ] RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

4 17 03

4 17 03

4 17 03

METHOD OF SUPPORT

FORMULATORS EXEMPTION

[ ] CITE ALL  
[ ] SELECTIVE  
[ ] NOT SUBMITTED  
[ ] NOT APPLICABLE  
[ ] INCORRECT/RESUB

[ ] SUBMITTED  
[ ] NOT SUBMITTED  
[ ] NOT APPLICABLE  
[ ] INCORRECT/RESUB

REVIEW(S) REQUESTED

DATA  
PACK #

DATE  
SENT

DUE  
DATE

DATE  
RETURNED

CHEMISTRY

EFFICACY

TOXICOLOGY

HED TOX.

ENVIRON. FATE

FISH/WILDLIFE

OTHER

STATUS

This letter is follow-up for 8633533

RESPONSE CODE

13

RESPONSE DATE

APR 17 2003

20



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 17 2003

Elizabeth Brown  
Agent for Ciba Specialty Chemicals  
c/o ChemReg International  
1990 Old Bridge Road, Suite 201  
Lake Ridge, VA 22192-2383

**Subject:** Irgaguard B102 Z (14.3% zinc)  
EPA File Symbol 40810-EL  
Your Pesticide Application Dated 9/13/2002;  
Re-Submission 11/4/02 (Revised Data Matrix);  
Re-Submission Dated 1/6/03 (Revised CSF, Label, Explodability Waiver)

The application and two re-submissions referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to register a new pesticide **Manufacturing Use Product (MP)**, are unacceptable. You must satisfy the following deficiencies.

**Acute Toxicity** (see attached review)

The six cited acute studies are not acceptable. The cited studies were conducted on EPA Reg. No. 40810-19 which has two active ingredients (ie., 2.2 % silver and 6.8% zinc). This proposed product has only one active ingredient (ie., zinc at 14.3%). You must satisfy the required acute toxicity data by submitting or citing either (A) more relevant studies with only zinc, (B) new studies using this product as the test substance, or (C) providing a scientific justification and rationale as to why the toxicity found in the cited studies which is based on two active ingredients, is the same as this product which has only one active ingredient. Note that a response to A, B, or C will undergo a science review.

**Product Chemistry** (see attached review)

1. The CSF dated 9/13/02 in the original application is unacceptable because it lists a [REDACTED] which is not in this product, and also listed incorrect suppliers. Apparently this CSF was incorrectly created from another related product.

2. The revised CSF dated 1/02/03 is also not acceptable. The terminology used on the CSF to describe the formula [REDACTED]

[REDACTED] does not match the description submitted data in MRID's 457770-01/-02 which list it as 14.3% zinc and 85.7% [REDACTED]

\*Inert ingredient information may be entitled to confidential treatment\*

CONCURRENCES 4							
SYMBOL							
SURNAME							
DATE							
							21



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Thus, the composition terminology used on the CSF must be identical with the composition terminology disclosed in the MRID's supporting the application.

3. The revised request for waiving explodability is acceptable. The original request was based on citing MRID 45618603 which was submitted to support EPA Reg. No. 40810-19 (a 2.2% silver; 6.8% zinc product). However, the chemistry review for EPA Reg No. 40810-19 did not mention whether explodability was acceptable or not. Therefore, your revised, stand-alone waiver request for this proposed application, now indicates actual explodability potential for this product, which was not stated prior.

## Required Labeling Changes

You must submit 5 copies of a revised label which makes the following changes listed below.

1. The original label dated 9/13/02 was found not acceptable because the uses did not contain adequate specificity for a MP product. For example, use of the proposed broad and undefined use terms such as "plastics, fibers, coatings, films, laminates, adhesives, sealants and other finished products", is unacceptable for a MP without more specificity. It has been the Agency policy that for this type of treated article MP product, the label must list at least the intended broad categories of treated articles.

2. The revised label dated 1/2/03 is also not acceptable because it still lacks adequate use specificity. As just one example, it is not clear what is intended by "specialty products". As some initial guidance for more specificity, you could use the end uses or categories listed on the proposed label for EPA File Symbol 40810-ET. For example, fibers could be specified as "fibers (human apparel and fibers for conveyor belts, bedding, packaging, recreational equipment, vehicle liners, carpets, etc.". As another example, the Agency and users need to know whether use in plastics include incorporation into human exposure concern articles such as diapers, baby pacifiers, toothbrush bristles, personal grooming ware, mouth guards, etc.

3. Change "This product is not approved for any food contact or human drinking water contact uses in the United States", to the following Agency preferred statement, "Do not use this product for any food contact or human drinking water contact uses.". Note that the Agency prefers and routinely uses direct and more enforceable "Do not use..." restriction statements, as opposed to the proposed less enforceable statement.

4. A review of all "Precautionary Statements" and "First Aid" labeling is reserved pending the resolution of the acute toxicology data gap.

## Efficacy

At the time of registration, you must have data in your files which supports all "antimicrobial agent" preservation claims. The Agency reserves the right to call for these data at any time. The Agency is not requesting that these data be submitted at this time.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

## Data Compensation

You have submitted a revised data matrix dated 11/4/02 which includes both product specific data listings, and TGAi data listings for the unregistered zinc active ingredient. This matrix is unacceptable. The following deficiencies must be satisfied by submitting a revised matrix.

### A. Product specific data listings

As per the acute toxicity comments listed above, the six cited product specific acute toxicity studies are not acceptable to support this product. You must either delete these, use other acceptable studies, or provide an acceptable scientific rationale for why the cited studies apply. An adequate justification for applicability was not submitted.

### B. Zinc TGAi generic data listings

The proposed uses require a standard non-food generic "Tier 1" data set for TGAi zinc consisting of the following data; product chemistry, hydrolysis, acute toxicity, one 90 day subchronic, developmental, mutagenicity battery, avian oral, fish, and daphnia. All of these required zinc data must be listed on the matrix and can be satisfied by citing the non-compensable MRID studies and/or public literature listed or mentioned (but not listed) in the "Zinc Salts" RED. This RED covers products with up to 99.9% zinc oxide and is therefore applicable to your 14.3% zinc product. A revised TGAi data matrix must be submitted which satisfies the "Tier 1" data set. You can either cite the RED MRID's/public literature, or use the "Cite-All" method of support.

The following are current deficiencies on the submitted TGAi zinc matrix dated 11/4/02. We previously advised you that the original matrix dated 9/13/02 was also unacceptable due to various deficiencies (eg., did not list all product specific chemistry MRID numbers, missing TGAi zinc product chemistry listings, etc.). All these deficiencies can be corrected by using appropriate zinc RED listings for each tier 1 requirement.

1. All TGAi zinc product chemistry listings are missing. Note there are only 11 TGAi product chemistry data requirements listed in 40 CFR Part 158. This can be fixed as discussed above.
2. The acute toxicity listings are shown a "Waived per RED". This is unacceptable because the RED waiver for these data was based on different uses than your proposed uses. You can satisfy the tier 1 acute data as discussed above.
3. The rest of the toxicity listings on the matrix can be satisfied as discussed above.

### D. Data certificates

You must submit a "Certificate With Respect To Citation of Data" to cover the product specific, and TGAi data for each unregistered active ingredient. One certificate can be used if the same method of support is used for both data compensation responsibilities (product specific, TGAi zinc), but you must so indicate this on the certificate.

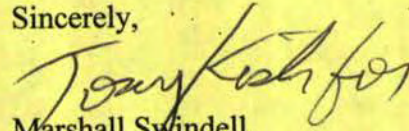
CONCURRENCES							
SYMBOL				Page 3 of 4			
SURNAME							
DATE							



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

If you have any questions about the comments in this letter, please feel free to contact Tony Kish at 703-308-9443, or myself at 703-308-6341.

Sincerely,



Marshall Swindell,  
Product Manager Team 33,  
Regulatory Management Branch I  
Antimicrobials Division (7510C)

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							



SUBMISSION BAR CODE #

633533  
8127807

REVIEWER

TK

## CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 40810-EL PM 33 ACTION CODE 173

DESCRIPTOR Revised CSF, label, exploitability waiver

[ ] CHILD RESISTANT PACKAGING: [ ] CERTIFICATION  
[ ] NON-RESIDENTIAL USE ONLY  
[ ] NOT APPLICABLE

REGISTRATION TYPE: [ ] CONDITIONAL [ ] UNCONDITIONAL

PROPOSED CLASSIFICATION: [ ] GENERAL [ ] RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

1 6 03

1 6 03

1 13 03

METHOD OF SUPPORT

FORMULATORS EXEMPTION

[ ] CITE ALL  
[ ] SELECTIVE  
[ ] NOT SUBMITTED  
[ ] NOT APPLICABLE  
[ ] INCORRECT/RESUB

[ ] SUBMITTED  
[ ] NOT SUBMITTED  
[ ] NOT APPLICABLE  
[ ] INCORRECT/RESUB

REVIEW(S) REQUESTED

DATA  
PACK #DATE  
SENTDUE  
DATEDATE  
RETURNED

CHEMISTRY

EFFICACY

TOXICOLOGY

HED TOX.

ENVIRON. FATE

FISH/WILDLIFE

OTHER

STATUS

Met w/ Liba on 4/6/03 to give them  
update, promised letters on 4/17/03


RESPONSE CODE

13

RESPONSE DATE

4/6/03



	United States	<input type="checkbox"/> Registration	OPP Identifier Number
	Environmental Protection Agency	<input type="checkbox"/> Amendment	
	Washington, DC 20460	<input checked="" type="checkbox"/> Other	

**Application for Pesticide – Section I**

1. Company/Product Number 40810-EL	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Irgaguard B 102 Z	PM # 33	
5. Name and Address of Applicant (Include ZIP Code) Ciba Specialty Chemicals Corporation 540 White Plains Road PO Box 2005 Tarrytown, New York 10591-9005 <input type="checkbox"/> Check if this is a new address	6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg No. _____ Product Name _____	

**Section - II**

<input type="checkbox"/> Amendment – Explain below	<input type="checkbox"/> Final printed labels in response to Agency letter dated
<input type="checkbox"/> Resubmission in response to Agency letter dated	<input type="checkbox"/> "Me Too" Application
<input type="checkbox"/> Notification – Explain below	<input checked="" type="checkbox"/> Other – Explain below


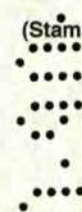
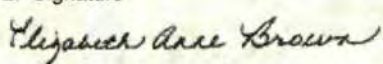
**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)  
Typographical correction to Ingredients Statement per PR 98-10.

Response to Agency phone call of January 2, 2003

**Section III**

1. Material This Product Will be Packaged in:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
*Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
					<input type="checkbox"/> Glass
					<input type="checkbox"/> Paper
					<input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of label directions <input type="checkbox"/> On Label <input type="checkbox"/> On Label accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

**Section IV**

1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Elizabeth Anne Brown	Title ChemReg International, LLC Authorized Agent	Telephone No. (Include Area Code) 703-492-7905
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received  (Stamped) 
2. Signature 	3. Title ChemReg International, LLC Authorized agent	
4. Typed Name Elizabeth Anne Brown	5. Date January 6, 2002	







# IRGAGUARD® B102 Z

Zinc zeolite

An antimicrobial agent for formulating use only.

Active ingredient:

Zinc (as elemental) .....	14.3%
Other ingredients.....	<u>85.7%</u>
Total.....	100.0%

**KEEP OUT OF REACH OF CHILDREN**

## CAUTION

### FIRST AID:

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

#### IF IN EYES

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye
- Call a poison control center or doctor for treatment advice

**FOR 24-HOUR EMERGENCY MEDICAL ASSISTANCE, CALL  
1-800-873-1138**

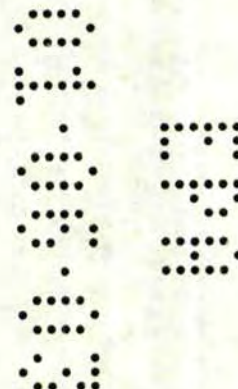
EPA Establishment No. 70404-AL-002

EPA Registration No. 40810-

Net Weight

Lot No.

Ciba Specialty Chemicals Corp.  
Plastic Additives  
540 White Plains Road  
Tarrytown, NY 10591





## **PRECAUTIONARY STATEMENTS**

### **HAZARDS TO HUMANS**

**CAUTION.** Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

### **DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Only for formulation into antimicrobial pesticides, for (1) use as Materials Preservatives in adhesives, industrial; caulks; paper (stored); papermaking; plastic/PVC/vinyl products; rubber products; sizing; specialty products; textiles/cordage products; textile-/textile fibers-making; coatings, industrial; (2) uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and (3) uses for experimental purposes that are in compliance with USEPA requirements.

Formulators using this product are responsible for providing data for the EPA registration of their formulated products.

### **ENVIRONMENTAL HAZARDS**

This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

### **STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage and disposal.

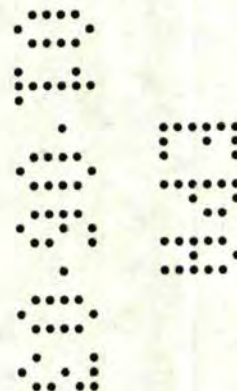
**Pesticide Storage:** Do not store in areas accessible to children. Keep away from direct sunlight.

**Pesticide Disposal:** Wastes from the use of this product may be disposed of on site or at an approved waste disposal facility.

**Container Disposal:** Completely empty bags into processing equipment where the pesticide is used. Then dispose of empty bag and box in sanitary landfill or by incineration, if allowed by state and local authorities.

**IRGAGUARD® is a trademark of Ciba Specialty Chemicals Corporation**

EPA Approval Date: NOT EPA APPROVED. Draft 01-02-2003





**Title**

**Irgaguard® B102 Z**  
Request for Waivers

**Data Requirements**

US-EPA Guideline Number OPPTS Series 830  
Product Properties Test Guidelines

830.6316 Explodability

**Author**

Thomas Barber  
Ciba Specialty Chemicals Corporation  
540 White Plains Road  
P.O. Box 2005  
Tarrytown, NY 10591-9005

**Sponsor**

Ciba Specialty Chemicals Corporation  
540 White Plains Road  
P.O. Box 2005  
Tarrytown, NY 10591-9005

**Study Completion Date**

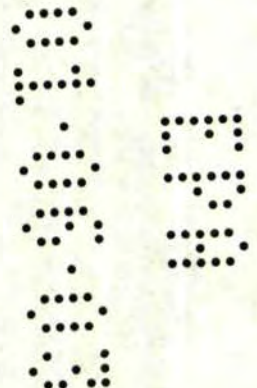
12/30/2002

**Study Number**

B102 Z-WR-2

**Total Pages**

4



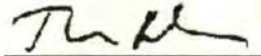


**Statement of Data Confidentiality**

No claim of confidentiality is made for any information contained in this submission on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C).

Company: Ciba Specialty Chemicals Corporation

Signature:



Thomas Barber

Title: Manager Product Compliance

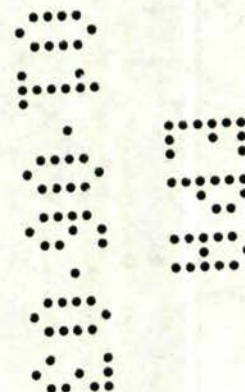
Date: 12/30/2002



The purpose of this submission is to request and justify a waiver from submission of data to fulfill certain data requirements which are not applicable to Irgaguard® B102 Z.

**OPPTS 830.6316 Explodability**

The data presented under MRID 45618303 applies to a silver-zinc glass antimicrobial of similar nature to Irgaguard B102 Z, consisting of ~2.2% ionically-bound silver and ~6.8% ionically-bound zinc. The explodability potential of the cited MRID product is expected to be identical to Irgaguard B102 Z. The product shows no explodability and neither the cited product or Irgaguard B102 Z has any constituents with chemical bonds or functional groups associated with explodable chemicals.





SUBMISSION BAR CODE # 5625031REVIEWER T Kish

FQPA

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTSFILE SYMBOL/REG NO. 40810-EL PM 33 ACTION CODE 173DESCRIPTOR Updated Data Matrix

[ ] CHILD RESISTANT PACKAGING: [ ] CERTIFICATION  
[ ] NON-RESIDENTIAL USE ONLY  
[ ] NOT APPLICABLE

REGISTRATION TYPE: [ ] CONDITIONAL [ ] UNCONDITIONAL

PROPOSED CLASSIFICATION: [ ] GENERAL [ ] RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

11	04	02
----	----	----

11	04	02
----	----	----

11	06	02
----	----	----

~~METHOD OF SUPPORT~~~~FORMULATORS EXEMPTION~~

[ ] CITE ALL  
[ ] SELECTIVE  
[ ] NOT SUBMITTED  
[ ] NOT APPLICABLE  
[ ] INCORRECT/RESUB

[ ] SUBMITTED  
[ ] NOT SUBMITTED  
[ ] NOT APPLICABLE  
[ ] INCORRECT/RESUB

REVIEW(S) REQUESTED

DATA  
PACK #DATE  
SENTDUE  
DATEDATE  
RETURNED

CHEMISTRY

EFFICACY

TOXICOLOGY

HED TOX.

ENVIRON. FATE

FISH/WILDLIFE

OTHER

STATUS

Science Reviews started with this submission

RESPONSE CODE

RESPONSE DATE



# ChemReg

INTERNATIONAL, LLC

1990 OLD BRIDGE ROAD, SUITE 201  
LAKE RIDGE, VIRGINIA 22192-2383

DIRECT: 703-492-7905  
MAIN: 703-492-0445  
Fax: 703-492-0668

E-MAIL: [brown@chemreg.com](mailto:brown@chemreg.com)  
WEB SITES: [www.chemreg.com](http://www.chemreg.com)  
[www.pesticide.net](http://www.pesticide.net)

**ELIZABETH A. BROWN, PH.D.**

November 4, 2002

Document Processing Desk  
Office of Pesticide Programs (7504C)  
U.S. Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202-4501

Attention: Marshall Swindell (PM 33)

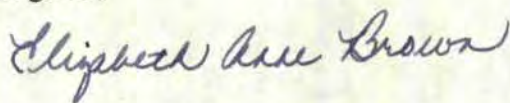
Re: Irgaguard B 102 Z, pending application (EPA File Symbol 40810-EL)

Dear Marshall:

On behalf of our client, Ciba Specialty Chemicals Corporation, enclosed please find updated data matrix forms (EPA Form 8570-35, Agency Use and Public File Copies) to identify the assigned MRIDs for studies submitted in support of this application for registration. Also enclosed is EPA Form 8570-1.

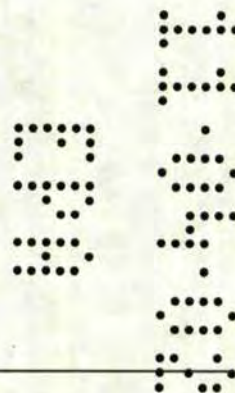
As a reminder, because there are no public health claims for this product, there is no requirement to address OPPTS 830.6317 (storage stability). Please let me know if you have any questions about this information.

Regards,



Elizabeth Anne Brown

cc: Ciba Specialty Chemicals Corporation



**CONSULTANTS TO SUCCESS<sup>SM</sup>**

Over One Hundred and Fifty Years of Combined Experience Assisting Chemical, Pesticide, Bio-Chemical and Life Science Companies on a Wide Range of Issues, Including Regulatory Strategies, Registration, Data Support and Compensation, Quality Assurance, Study Design and Scientific Matters.





United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

**Application for Pesticide – Section I**

1. Company/Product Number 40810-EL	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Irgaguard® B 102 Z	PM # 33	
5. Name and Address of Applicant (Include ZIP Code) Ciba Specialty Chemical Corporation 540 White Plains Road P.O. Box 2005 Tarrytown, NY 10591-9005 <input type="checkbox"/> Check if this is a new address	6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg No. <u>40810-17</u> Product Name <u>Irgaguard B8000</u>	

**Section - II**

<input type="checkbox"/> Amendment – Explain below	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input type="checkbox"/> Notification – Explain below	<input checked="" type="checkbox"/> Other – Explain below

**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)**Section III**

1. Material This Product Will be Packaged in:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
<b>*Certification must be submitted</b>		If "Yes" Unit Packaging wgt.	No. per container	<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input checked="" type="checkbox"/> Other (Specify) <u>2 plastic bags (10 kg ea) in a cardboard box</u>	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 2 x 10 kg		5. Location of label directions <input type="checkbox"/> On Label <input checked="" type="checkbox"/> On Label accompanying product	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

**Section IV**

1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Thomas Barber		Title Manager, Product Compliance		Telephone No. (Include Area Code) (914) 785-4311	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law					6. Date Application Received    
2. Signature 		3. Title Manager, Product Compliance			
4. Typed Name Thomas Barber		5. Date 11/4/2002			





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: November 4, 2002	EPA Reg No./ File Symbol 40810-EL	Page 1 of 3
Applicant's/Registrant's Name and Address: Ciba Specialty Chemicals Corporation 540 White Plains Road PO Box 2005 Tarrytown, NY 10591-9005		
Product: Irgaguard® B102 Z Manufacturing Use		
Ingredient: zinc (PC 129015)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<b>PRODUCT SPECIFIC DATA</b>					
OPPTS 830.1550	Product Identity and Composition	45777001	Ciba Specialty Chemicals	Own	
OPPTS 830.1600	Description of Starting Materials	45777001	Ciba Specialty Chemicals	Own	
OPPTS 830.1620	Description of the production Process	45777001	Ciba Specialty Chemicals	Own	
OPPTS 830.1670	Discussion of the Formation of Impurities	45777001	Ciba Specialty Chemicals	Own	
OPPTS 830.1700	Preliminary analysis	45777001	Ciba Specialty Chemicals	own	
OPPTS 830.1750	Certified Limits	45777001	Ciba Specialty Chemicals	Own	
OPPTS 830.1800	Enforcement analytical method	45777001	Ciba Specialty Chemicals	Own	
OPPTS 830.6303	Physical state	45777002	Ciba Specialty Chemicals	Own	
OPPTS 830.7000	pH	45777002	Ciba Specialty Chemicals	Own	
OPPTS 830.6314	Oxidation/reduction: chemical incompatibility	Waiver	Ciba Specialty Chemicals	Own	See footnote 1
OPPTS 830.6320	Corrosion characteristics	Waiver	Ciba Specialty Chemicals	Own	See footnote 1
OPPTS 830.6302	Color	45777002	Ciba Specialty Chemicals	Own	
OPPTS 830.6304	Odor	45777002	Ciba Specialty Chemicals	Own	
OPPTS 830.6315	Flammability	Waiver	Ciba Specialty Chemicals	Own	See footnote 1
OPPTS 830.6316	Explosibility	45618603	Ciba Specialty Chemicals	Own	See footnote 2
OPPTS 830.6319	Miscibility	Waiver	Ciba Specialty Chemicals	Own	See footnote 1
OPPTS 830.7100	Viscosity	Waiver	Ciba Specialty Chemicals	Own	See footnote 1
OPPTS 830.7300	Density	45777002	Ciba Specialty Chemicals	Own	
OPPTS 870.1100	Acute oral toxicity - rat	45618604	Ciba Specialty Chemicals	Own	See footnote 2
OPPTS 870.1200	Acute dermal toxicity - rat	45618605	Ciba Specialty Chemicals	Own	See footnote 2
OPPTS 870.1300	Acute inhalation toxicity	45618606	Ciba Specialty Chemicals	Own	See footnote 2
OPPTS 870.2400	Primary eye irritation - rabbit	45618607	Ciba Specialty Chemicals	Own	See footnote 2

Signature

Name and Title  
Thomas Barber  
Manager Product ComplianceDate  
11/4/2002





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

## DATA MATRIX

EPA Reg No./ File Symbol  
40810-EL

Page 2 of 3

Product: Irgaguard® B102 Z Manufacturing Use

Ciba Specialty Chemicals Corporation  
540 White Plains Road  
PO Box 2005  
Tarrytown, NY 10591-9005

Date: November 4, 2002

Applicant's/Registrant's Name and Address:

Ingredient: zinc (PC 129015)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 870.2500	Primary dermal irritation	45618608	Ciba Specialty Chemicals	Own	See footnote 2
OPPTS 870.2600	Dermal sensitization	45618609	Ciba Specialty Chemicals	Own	See footnote 2
<b>GENERIC DATA - ZINC</b>					
870.1100	Acute oral toxicity - rat	Waived	Per RED	RED	
870.1200	Acute dermal toxicity - rat	Waived	Per RED	RED	
870.1300	Acute inhalation toxicity	Waived	Per RED	RED	
870.2400	Primary eye irritation - rabbit	Waived	Per RED	RED	
870.2500	Primary dermal irritation	Waived	Per RED	RED	
870.2600	Dermal sensitization	Waived	Per RED	RED	
870.3250	90 day dermal toxicity - rodent	Waived	Per RED	RED	
870.3700	Developmental toxicity - rodent	Waived	Per RED	RED	
870.5265	In vitro mutagenicity	Waived	Per RED	RED	
870.5300	Mutagenicity - mammalian cells in culture	Waived	Per RED	RED	
870.5380	In vivo cytogenetics	Waived	Per RED	RED	
850.1010	Daphnia acute toxicity	42032806 155227	Kanebo Monsanto	Per old	Waived for Most zinc salts in RED
850.1075	Acute toxicity - fish	155224 155228	Monsanto	old	Waived for Most zinc salts in RED
850.2100	Avian Acute toxicity	42070901 155226	Kanebo Monsanto	Per old	Waived for Most zinc salts in RED

Signature

Name and Title  
Thomas Barber  
Manager Product ComplianceDate  
11/4/2002



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: November 4, 2002	EPA Reg No./ File Symbol 40810-EL	Page 3 of 3
Applicant's/Registrant's Name and Address: Ciba Specialty Chemicals Corporation 540 White Plains Road PO Box 2005 Tarrytown, NY 10591-9005	Product: Irgaguard® B102 Z Manufacturing Use	
Ingredient: zinc (PC 129015)		


Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.2120	Hydrolysis	Waived	Per RED	RED	

Footnote 1: Request for Waivers submitted for these tests. Footnote 2: See Request for Waivers for explanation/justification.

835.2120

30.9.9.11

39

Signature 	Name and Title Thomas Barber Manager Product Compliance	Date 11/4/2002
--	---	-------------------





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: November 4, 2002	EPA Reg No./ File Symbol 40810-EL	Page 1 of 3
Applicant's/Registrant's Name and Address: Ciba Specialty Chemicals Corporation 540 White Plains Road PO Box 2005 Tarrytown, NY 10591-9005	Product: Irgaguard® B102 Z Manufacturing Use	
Ingredient: zinc (PC 129015)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Ciba Specialty Chemicals	Own	
			Ciba Specialty Chemicals	Own	
			Ciba Specialty Chemicals	Own	
			Ciba Specialty Chemicals	Own	
			Ciba Specialty Chemicals	own	
			Ciba Specialty Chemicals	Own	
			Ciba Specialty Chemicals	Own	
			Ciba Specialty Chemicals	Own	
			Ciba Specialty Chemicals	Own	
			Ciba Specialty Chemicals	Own	
			Ciba Specialty Chemicals	Own	See footnote 1
			Ciba Specialty Chemicals	Own	See footnote 1
			Ciba Specialty Chemicals	Own	
			Ciba Specialty Chemicals	Own	
			Ciba Specialty Chemicals	Own	See footnote 1
			Ciba Specialty Chemicals	Own	See footnote 2
			Ciba Specialty Chemicals	Own	See footnote 1
			Ciba Specialty Chemicals	Own	See footnote 1
			Ciba Specialty Chemicals	Own	
			Ciba Specialty Chemicals	Own	See footnote 2
			Ciba Specialty Chemicals	Own	See footnote 2
			Ciba Specialty Chemicals	Own	See footnote 2
			Ciba Specialty Chemicals	Own	See footnote 2

Signature

Name and Title  
Thomas Barber  
Manager Product ComplianceDate  
11/4/2002





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: November 4, 2002	EPA Reg No./ File Symbol 40810-EL	Page 2 of 3
Applicant's/Registrant's Name and Address: Ciba Specialty Chemicals Corporation 540 White Plains Road PO Box 2005 Tarrytown, NY 10591-9005	Product: Irgaguard® B102 Z Manufacturing Use	
Ingredient: zinc (PC 129015)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Ciba Specialty Chemicals	Own	See footnote 2
			Ciba Specialty Chemicals	Own	See footnote 2
			Per RED	RED	
			Per RED	RED	
			Per RED	RED	
			Per RED	RED	
			Per RED	RED	
			Per RED	RED	
			Per RED	RED	
			Per RED	RED	
			Per RED	RED	
			Per RED	RED	
			Per RED	RED	
			Per RED	RED	
			Per RED	RED	
			Per RED	RED	
			Kanebo Monsanto	Per old	Waived for Most zinc salts in RED
			Monsanto	old	Waived for Most zinc salts in RED
			Kanebo Monsanto	Per old	Waived for Most zinc salts in RED

Signature 	Name and Title Thomas Barber Manager Product Compliance	Date 11/4/2002
---------------	---	-------------------





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: November 4, 2002	EPA Reg No./ File Symbol 40810-EL	Page 3 of 3
Applicant's/Registrant's Name and Address: Ciba Specialty Chemicals Corporation 540 White Plains Road PO Box 2005 Tarrytown, NY 10591-9005	Product: Irgaguard® B102 Z Manufacturing Use	
Ingredient: zinc (PC 129015)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Per RED	RED	

Footnote 1: Request for Waivers submitted for these tests. Footnote 2: See Request for Waivers for explanation/justification.

42

200011

42

Signature

Name and Title  
Thomas Barber  
Manager Product ComplianceDate  
11/4/2002

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public File Copy





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

December 19, 2002

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 40810-EL  
Irgaguard B 102 Z  
DP Barcode: D287262  
Case No: 64209

To: Marshall Swindell PM 33 / Tony Kish, Team Reviewer  
Regulatory Management Branch I  
Antimicrobials Division (7510C)

From: Robert A. Turpin, Scientist *R.T.*  
Chemistry/Toxicology Team  
Product Science Branch  
Antimicrobials Division (7510C)

Through: Karen Hicks, Team Leader  
Chemistry and Toxicology Team  
Product Science Branch  
Antimicrobials Division (7510C)

*K. P. Hicks*  
*12/19/02*

Michele E. Wingfield, Chief  
Product Science Branch  
Antimicrobials Division (7510C)

Applicant: Ciba Specialty Chemicals Corporation

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Zinc .....	14.30
<u>Other Ingredient(s):</u>	85.70
Total:	100%



BACKGROUND: The applicant has submitted an application for the registration of its product, Irgaguard B 102 Z. In support of the submission, the applicant has cited toxicology studies of a previously registered product, EPA Reg. No. 40810-19, in which the active ingredients are zinc and silver. The applicant is claiming similarity between the products. The Product Science Branch has performed the primary review.

RECOMMENDATIONS (PSB findings):

The acute toxicity studies cited in support of the subject application for registration are unacceptable. The cited studies were performed using a formulation composed of two active ingredients, one of which was zinc at 6.8% the second active being silver at 2%. The applicant must submit studies of the composition for which registration is being sought or of compositions of like formula, i.e., zinc only as the active ingredient.

The acute toxicity profile for Reg. No. 40810-EL is currently:

acute oral toxicity	U	Unacceptable
acute dermal toxicity	U	Unacceptable
acute inhalation toxicity	U	Unacceptable
primary eye irritation	U	Unacceptable
primary skin irritation	U	Unacceptable
dermal sensitization	U	Unacceptable

LABELING:

Undetermined in the absence of acceptable toxicity studies.



DP BARCODE: D287262

CASE: 064209  
SUBMISSION: S625031

DATA PACKAGE RECORD  
BEAN SHEET

DATE: 12/10/02  
Page 1 of 1

\* \* \* CASE/SUBMISSION INFORMATION \* \* \*

CASE TYPE: REGISTRATION ACTION: 173 RESB-FQPA ROUTINE ME TOO  
CHEMICALS: 129015 Zinc 14.3000%

ID#: 040810-EL IRGAGUARD B 102 Z  
COMPANY: 040810 CIBA SPECIALTY CHEMICALS CORPORATION  
PRODUCT MANAGER: 33 MARSHALL SWINDELL 703-308-6341 ROOM: CS1 6B  
PM TEAM REVIEWER: TONY KISH 703-308-9443 ROOM: CS1 3W69  
RECEIVED DATE: 11/04/02 DUE OUT DATE: 02/02/03

\* \* \* DATA PACKAGE INFORMATION \* \* \*

DP BARCODE: 287262 EXPEDITE: Y DATE SENT: 12/10/02 DATE RET.: / /  
CHEMICAL: 129015 Zinc  
P TYPE: 001

ASSIGNED TO	DATE IN	DATE OUT	ADMIN DUE DATE: 01/24/03
DIV : AD	12/12/02	/ /	NEGOT DATE: 1/2/03
BRAN: PSB	12/12/02	/ /	PROJ DATE: 12/20/02
SECT: CTT	12/12/02	/ /	
REVR: Bob.T.	12/13/02	/ /	
CONTR:	/	/ /	

\* \* \* DATA REVIEW INSTRUCTIONS \* \* \*

Karen: We need acute tox reviewer to determine if the cited acute tox studies on the matrix, which were done on a 2.2% silver and 6.8% zinc product (40810-19), satisfy the acute tox for this proposed product. Do not review the cited studies, they were already found acceptable in 40810-19. Also need reviewer to comment on appropriateness of precautionary labeling/SOPT, etc. This BEAN is being sent late. Can you have BOB TURPIN review this because he did the related one D284764. Thks, Tony.

\* \* \* DATA PACKAGE EVALUATION \* \* \*

No evaluation is written for this data package

\* \* \* ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION \* \* \*

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
-------	----------------	----------	----------	-----	-----	-------

V - please copy bean for me. TY!



45618604 Wilson, C. (2002) An Acute Oral Toxicity Study in Rats with TKA  
45039: Final Report: Lab Project Number: 3466.32. Unpublished  
study prepared by Springborn Laboratories, Inc. 22 p. {OPPTS  
870.1100}

TRADE SECRET STATUS: 90 TRADE SECRET STATUS DATE: 0

M=GENERAL PURPOSE MENU; D=DISPLAY INDEXING MENU; RETURN TO CONTINUE

*40810-19*  
*Reviewed acceptable*



12/10/02

REFERENCE FILES SYSTEM

PAGE 1

Product Formulation Data

40810-19 IRGAGUARD B502 I

PC CODE	PERCENT	CHEMICAL NAME
---------	---------	---------------

72501	02.2000	Silver
129015	06.8000	Zinc

*acuter Run on this formula*





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

DATA MATRIX

Date: November 4, 2002	EPA Reg No./ File Symbol 40810-EL	Page 1 of 3
Applicant's/Registrant's Name and Address: Ciba Specialty Chemicals Corporation 540 White Plains Road PO Box 2005 Tarrytown, NY 10591-9005		Product: Irgaguard® B102 Z Manufacturing Use
Ingredient: zinc (PC 129015)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<b>PRODUCT SPECIFIC DATA</b>					
OPPTS 830.1550	Product Identity and Composition	45777001	Ciba Specialty Chemicals	Own	
OPPTS 830.1600	Description of Starting Materials	45777001	Ciba Specialty Chemicals	Own	
OPPTS 830.1620	Description of the production Process	45777001	Ciba Specialty Chemicals	Own	
OPPTS 830.1670	Discussion of the Formation of Impurities	45777001	Ciba Specialty Chemicals	Own	
OPPTS 830.1700	Preliminary analysis	45777001	Ciba Specialty Chemicals	Own	
OPPTS 830.1750	Certified Limits	45777001	Ciba Specialty Chemicals	Own	
OPPTS 830.1800	Enforcement analytical method	45777001	Ciba Specialty Chemicals	Own	
OPPTS 830.6303	Physical state	45777002	Ciba Specialty Chemicals	Own	
OPPTS 830.7000	pH	45777002	Ciba Specialty Chemicals	Own	
OPPTS 830.6314	Oxidation/reduction: chemical incompatibility	Waiver	Ciba Specialty Chemicals	Own	See footnote 1
OPPTS 830.6320	Corrosion characteristics	Waiver	Ciba Specialty Chemicals	Own	See footnote 1
OPPTS 830.6302	Color	45777002	Ciba Specialty Chemicals	Own	
OPPTS 830.6304	Odor	45777002	Ciba Specialty Chemicals	Own	
OPPTS 830.6315	Flammability	Waiver	Ciba Specialty Chemicals	Own	See footnote 1
OPPTS 830.6316	Explosibility	45618603	Ciba Specialty Chemicals	Own	See footnote 2
OPPTS 830.6319	Miscibility	Waiver	Ciba Specialty Chemicals	Own	See footnote 1
OPPTS 830.7100	Viscosity	Waiver	Ciba Specialty Chemicals	Own	See footnote 1
OPPTS 830.7300	Density	45777002	Ciba Specialty Chemicals	Own	
OPPTS 870.1100	Acute oral toxicity - rat	45618604	Ciba Specialty Chemicals	Own	See footnote 2
OPPTS 870.1200	Acute dermal toxicity - rat	45618605	Ciba Specialty Chemicals	Own	See footnote 2
OPPTS 870.1300	Acute inhalation toxicity	45618606	Ciba Specialty Chemicals	Own	See footnote 2
OPPTS 870.2400	Primary eye irritation - rabbit	45618607	Ciba Specialty Chemicals	Own	See footnote 2

Signature 	Name and Title Thomas Barber Manager Product Compliance	Date 11/4/2002
---------------	---	-------------------



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.  
WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: November 4, 2002

EPA Reg No./ File Symbol  
40810-EL

Page 2 of 3

Applicant's/Registrant's Name and Address:

Ciba Specialty Chemicals Corporation  
540 White Plains Road  
PO Box 2005  
Tarrytown, NY 10591-9005

Product: Irgaguard® B102 Z Manufacturing Use

Ingredient: zinc (PC 129015)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 870.2500	Primary dermal irritation	45618608	Ciba Specialty Chemicals	Own	See footnote 2
OPPTS 870.2600	Dermal sensitization	45618609	Ciba Specialty Chemicals	Own	See footnote 2
<b>GENERIC DATA - ZINC</b>					
870.1100	Acute oral toxicity - rat	Waived	Per RED	RED	
870.1200	Acute dermal toxicity - rat	Waived	Per RED	RED	
870.1300	Acute inhalation toxicity	Waived	Per RED	RED	
870.2400	Primary eye irritation - rabbit	Waived	Per RED	RED	
870.2500	Primary dermal irritation	Waived	Per RED	RED	
870.2600	Dermal sensitization	Waived	Per RED	RED	
870.3250	90 day dermal toxicity - rodent	Waived	Per RED	RED	
870.3700	Developmental toxicity - rodent	Waived	Per RED	RED	
870.5265	In vitro mutagenicity	Waived	Per RED	RED	
870.5300	Mutagenicity - mammalian cells in culture	Waived	Per RED	RED	
870.5380	In vivo cytogenetics	Waived	Per RED	RED	
850.1010	Daphnia acute toxicity	42032806 155227	Kanebo Monsanto	Per old	Waived for Most zinc salts in RED
850.1075	Acute toxicity - fish	155224 155228 ...	Monsanto	old	Waived for Most zinc salts in RED
850.2100	Avian Acute toxicity	42370901 155226	Kanebo Monsanto	Per old	Waived for Most zinc salts in RED
Signature	Name and Title Thomas Barber Manager Product Compliance		Date 11/4/2002		

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: November 4, 2002	EPA Reg No./ File Symbol 40810-EL	Page 3 of 3
Applicant's/Registrant's Name and Address: Ciba Specialty Chemicals Corporation 540 White Plains Road PO Box 2005 Tarrytown, NY 10591-9005		
Product: Irgaguard® B102 Z Manufacturing Use		
Ingredient: zinc (PC 129015)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.2120	Hydrolysis	Waived	Per RED	RED	

Footnote 1: Request for Waivers submitted for these tests. Footnote 2: See Request for Waivers for explanation/justification.

43

30.99.11

50

Signature

Name and Title  
Thomas Barber  
Manager Product ComplianceDate  
11/4/2002

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy



**Title**

**Irguard® B102 Z**  
Request for Waivers

**Data Requirements**

US-EPA Guideline Number OPPTS Series 830  
Product Properties Test Guidelines

830.6314 Oxidation/Reduction: Chemical Incompatibility  
830.6320 Corrosion Characteristics  
830.6315 Flammability  
830.6316 Explodability  
830.6319 Miscibility  
830.7100 Viscosity  
870.1100 Acute Oral Toxicity – rat  
870.1200 Acute Dermal Toxicity – rat  
870.1300 Acute Inhalation Toxicity  
870.2400 Primary Eye Irritation – rabbit  
870.2500 Primary Dermal Irritation  
870.2600 Dermal Sensitization

**Author**

Thomas Barber  
Ciba Specialty Chemicals Corporation  
540 White Plains Road  
P.O. Box 2005  
Tarrytown, NY 10591-9005

**Sponsor**

Ciba Specialty Chemicals Corporation  
540 White Plains Road  
P.O. Box 2005  
Tarrytown, NY 10591-9005

**Study Completion Date**

9/13/2002

**Study Number**

B102 Z-WR

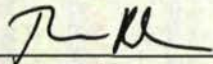
**Total Pages**



**Statement of Data Confidentiality**

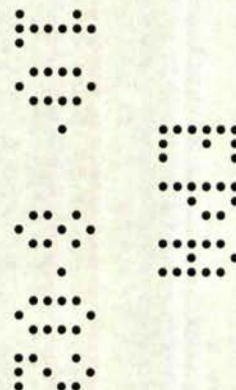
No claim of confidentiality is made for any information contained in this submission on the basis of its falling within the scope of FIFRA § 10(d)(1)(A), (B), or (C).

Company: Ciba Specialty Chemicals Corporation

Signature:   
Thomas Barber

Title: Manager Product Compliance

Date: 9/13/2002

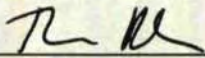




### Good Laboratory Practices Statement

This paper, titled "Irgaguard® B102 Z Request for Waivers" is a discussion and presentation of information. No data are being submitted that are subject to Good Laboratory Practice Standards (40 CFR Part 160).

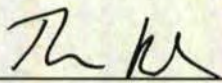
Sponsor:

Signature:   
Thomas Barber

Title: Manager Product Compliance

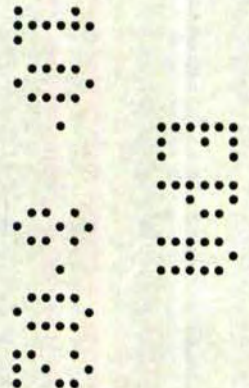
Date: 9/13/2002

Author/Submitter:

Signature:   
Thomas Barber

Title: Manager Product Compliance

Date: 9/13/2002





The purpose of this submission is to request and justify a waiver from submission of data to fulfill certain data requirements which are not applicable to Irgaguard® B102 Z.

**OPPTS 830.6314 Oxidation/Reduction: Chemical Incompatibility**

This data requirement is not applicable to Irgaguard® B102 Z because the product, which is a mixture of inorganic compounds, will not react when placed in contact with oxidizing or reducing agents.

**OPPTS 830.6320 Corrosion Characteristics**

This data requirement is not applicable to Irgaguard® B102 Z because the product, which is a mixture of inorganic compounds, will not react with polyethylene bags in which the product is commercially supplied.

**OPPTS 830.6315 Flammability**

This data requirement is not applicable to Irgaguard® B102 Z because the product is an inorganic solid material, and not a liquid.

**OPPTS 830.6316 Explodability**

The data presented under this MRID applies to a silver-zinc glass antimicrobial of similar nature, consisting of ~6.8% ionically-bound zinc. The explodability potential of the cited MRID product is expected to be identical to Irgaguard B102 Z.

**OPPTS 830.6319 Miscibility**

This data requirement is not applicable to Irgaguard® B102 Z because the product is not an emulsifiable liquid intended for dilution with petroleum solvents.

**OPPTS 830.7100 Viscosity**

This data requirement is not applicable to Irgaguard® B102 Z because the product is not a liquid.

**OPPTS 870.1100 Acute Oral Toxicity – rat**

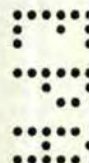
The data presented under this MRID applies to a silver-zinc glass antimicrobial of similar nature, consisting of ~6.8% ionically-bound zinc. The toxicological profiles of the cited MRID product is expected to be identical to Irgaguard B102 Z.

**OPPTS 870.1200 Acute Dermal Toxicity – rat**

The data presented under this MRID applies to a silver-zinc glass antimicrobial of similar nature, consisting of ~6.8% ionically-bound zinc. The toxicological profiles of the cited MRID product is expected to be identical to Irgaguard B102 Z.



of similar nature,



of similar nature,





**OPPTS 870.1300 Acute Inhalation Toxicity**

The data presented under this MRID applies to a silver-zinc glass antimicrobial of similar nature, consisting of ~6.8% ionically-bound zinc. The toxicological profiles of the cited MRID product is expected to be identical to Irgaguard B102 Z.

**OPPTS 870.2400 Primary Eye Irritation – rabbit**

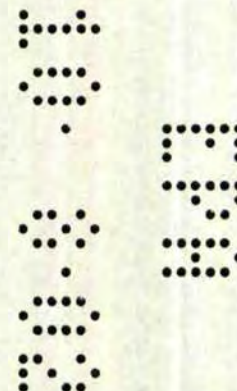
The data presented under this MRID applies to a silver-zinc glass antimicrobial of similar nature, consisting of ~6.8% ionically-bound zinc. The toxicological profiles of the cited MRID product is expected to be identical to Irgaguard B102 Z.

**OPPTS 870-2500 Primary Dermal Irritation**

The data presented under this MRID applies to a silver-zinc glass antimicrobial of similar nature, consisting of ~6.8% ionically-bound zinc. The toxicological profiles of the cited MRID product is expected to be identical to Irgaguard B102 Z.

**OPPTS 870.2600 Dermal Sensitization**

The data presented under this MRID applies to a silver-zinc glass antimicrobial of similar nature, consisting of ~6.8% ionically-bound zinc. The toxicological profiles of the cited MRID product is expected to be identical to Irgaguard B102 Z.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460



OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES  
Antimicrobials Division

January 7, 2003

**SUBJECT: PRODUCT CHEMISTRY REVIEW OF: Irgaguard B 102 Z**

**DP Barcode: D287263**

**Reg. No. Or File Symbol: 40810-EL**

**Manufacturing-use [X] OR**

**End-use Product [ ]**

**TO:** Marshall Swindell PM 33 / Tony Kish, Team Reviewer  
Regulatory Management Branch I  
Antimicrobials Division (7510C)

**FROM:** Robert A. Turpin, Chemist *R.A.T.*  
Product Science Branch, CT Team  
Antimicrobials Division (7510C)

**THRU:** Karen P. Hicks, CT Team Leader  
Product Science Branch  
Antimicrobials Division (7510C)

*K.P. Hicks*  
1/9/03

**THRU:** Michele E. Wingfield, Chief  
Product Science Branch  
Antimicrobials Division (7510C)

**Product Formulation**

Active Ingredient(s)	% by wt.
Zinc .....	14.30

**BACKGROUND:** The applicant has submitted an application for an MUP registration of its product, Irgaguard B 102 Z, which is similar in composition to Irgaguard B8000, EPA Reg. No. 40810-17. Irgaguard B8000 is a composition of zinc (6.8%) and silver in a zeolite matrix as compared to the zinc (14.3%) of the current submission. In support of the application has been submitted a Confidential Statement of Formula, a draft label, requests for waivers of certain data requirements, and data to fulfill the requirements of OPPTS Test Series 830.1550, -1600, -1620, -1670, -1700, -1750, -1800, -6302, -6303, -6304, -7000, and -7300. The Product Science Branch has performed the primary review.



## **FINDINGS:**

1. The Confidential Statement of Formula of the subject composition is not acceptable. In response to a telephone conversation with between Tony Kish and Robert Turpin of the Agency and Elizabeth Brown, representing the applicant, the applicant submitted a revised Confidential Statement of Formula indicating a [REDACTED] without a breakdown of the components. According to the supporting data submitted the composition is comprised of 14.3% zinc and [REDACTED]. The composition of the [REDACTED] in the original submission did not conform with the composition disclosed in the MRID supporting the application.
2. The requests for waivers of the requirements to perform tests OPPTS 830.6314 - Oxidation/Reduction; 830.6315 - Flammability; 830.6316 - Explodability; 830.6319 - Miscibility; and, 830.7100 - Viscosity are granted.
3. The studies of the physical/chemical properties reported in MRID #457770-01 are acceptable to the Agency. It is noted that the certified limits of the active ingredient are extended beyond the default limits of 40 CFR 158.175. The extended limits are justified based on the nature of the [REDACTED] and production process.
4. The ingredient section and the statement of Storage and Disposal on the draft label are acceptable to the Agency.
5. The data presented did not include a study of storage stability.

## **RECOMMENDATIONS:**

1. The applicant is required to submit to the Agency a Confidential Statement of Formula of the subject product which separates the primary constituents (zinc and [REDACTED] of the composition. Further, the type of [REDACTED] used in the product and disclosed on the Confidential Statement of Formula must agree with the [REDACTED] of the supporting MSDS. The [REDACTED] is disclosed as [REDACTED].
2. The applicant is required to submit to the Agency a twelve month study of the stability of the product using the guidelines of 830.6317.



**PRODUCT CHEMISTRY REVIEW**

4. **CONFIDENTIAL STATEMENT OF FORMULA**

4a. Type of formulation and source registration

- Non-integrated formulation system [X]
  - Are all TGAs used registered? Yes [ ] No [X]
- Integrated formulation system [ ]
- if "ME-TOO", specify EPA Reg. # of existing product:

4b. Clearance of inerts for non-food or food use:

Cleared for food use under 40 CFR §180.1001: Yes [ ] No [ ] NA [X]

4c. Physical state of product: Solid

4d. The chemical IDs and analytical information (including that for the TGAs), density, pH, and flammability are consistent with that given in 830, Part B

Yes [X] No [ ]

4h. NCs and CLs are acceptable: Yes [ ] No [X] Not acceptable [X]

4i. Active ingredient (s)	NC	LCL	UCL
Zinc	14.3%	13.0%	15.5%

4j. For products produced by an integrated formulation system:

- All impurities of toxicological significance have a UCL?  
Yes [ ] No [ ] Not applicable [X]
- All impurities of  $\geq 0.1\%$  in the product have been identified?  
Yes [ ] No [ ] Not applicable [X]



5. PRODUCT LABEL

5a. The active ingredients statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA? Yes ☐ No ☒

5b. The formulation contains one of the following:

- 10% or more of a petroleum distillate: Yes ☐ No ☒
- 1.0% or more of methyl alcohol: Yes ☐ No ☒
- Sodium nitrite at any level: Yes ☐ No ☒
- a toxic List 1 inert at any level: Yes ☐ No ☒
- arsenic in any form: Yes ☐ No ☒

5c. If Yes to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes ☐ No ☐ Not applicable ☒

5d. The appropriate warning statement regarding flammability or explosive characteristics of the product are listed on the label?  
Yes ☐ No ☐ Not applicable ☒

5e. The storage and disposal instructions for the pesticide and container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses? Yes ☒ No ☐ Not on label

5f. Does the product require an expiration date at which time the NC falls below the LCL (based on the one year storage stability data or other information)?  
Yes ☐ No ☒



2.

**PRODUCT CHEMISTRY (830 Series, Part B)**

Guideline	Acceptance of Information	MRID No.
830.1550 <sup>1</sup> Product Identity	A	457770-01
830.1600 Description of Materials	A	457770-01
830.1620 Production Method <sup>2</sup>	A	457770-01
830.1650 Formulation process <sup>3</sup>	NA	
830.1670 Formation of impurities <sup>4</sup>	A	457770-01
830.1700 Preliminary Analysis <sup>5</sup>	A	457770-01
830.1750 Certified Limits <sup>6</sup>	U	Confidential Statement of Formula & 457770-01
830.1800 Analytical Method <sup>7</sup> - ICP Analysis	A	457770-01

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

<sup>1</sup>See Confidential Appendix A for additional information

<sup>2</sup>For MP/EP products produced by an integrated formulation system.

<sup>3</sup>For products from a TGAI or MP.

<sup>4</sup>May be waived unless actual/possible impurities are of toxicological concern.


<sup>5</sup>Five batch analysis required for products produced by an integrated formulation system.

<sup>6</sup>If different from standard CIs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

<sup>7</sup>Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.



6b. <u>Physical/Chemical Properties</u> *	Acceptance of data	Value or qualitative description	MRID No.
830.6302 Color	A	White	457770-02
830.6303 Physical state	A	powder	457770-02
830.6303 Odor	A	No odor	457770-02
830.7200 Melting point	G	Not addressed	
830.7220 Density/Relative density/bulk density	A	2.187+/-0.004 g/cm <sup>3</sup>	457770-02
830.7000 pH <sup>1</sup>	A	8.7+/-1 @ 22°C	457770-02
830.6314 Oxidation/Reduction	W		
830.6315 Flammability	W		
830.6317 Storage stability	G	No study presented	
830.7100 Viscosity	W		
830.6319 Miscibility <sup>2</sup>	W		
830.6320 Corrosion Character.	W		
830.6321 Dielectric breakdown	NA		

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; G=data gap; =requires upgrading; W=waived; E=EPA estimate.

\* Provide brief description, e.g., color--yellow or property value, e.g., density 1.25 g/cc; Unless otherwise indicated, the property should be at 25 °C.

<sup>1</sup> If product is dispersible with water

<sup>2</sup> If product is an emulsifiable liquid







**Title**

**Irgauard® B102 Z**  
Request for Waivers

**Data Requirements**

US-EPA Guideline Number OPPTS Series 830  
Product Properties Test Guidelines

830.6314 Oxidation/Reduction: Chemical Incompatibility  
830.6320 Corrosion Characteristics  
830.6315 Flammability  
830.6316 Explodability  
830.6319 Miscibility  
830.7100 Viscosity  
870.1100 Acute Oral Toxicity – rat  
870.1200 Acute Dermal Toxicity – rat  
870.1300 Acute Inhalation Toxicity  
870.2400 Primary Eye Irritation – rabbit  
870.2500 Primary Dermal Irritation  
870.2600 Dermal Sensitization

**Author**

Thomas Barber  
Ciba Specialty Chemicals Corporation  
540 White Plains Road  
P.O. Box 2005  
Tarrytown, NY 10591-9005

**Sponsor**

Ciba Specialty Chemicals Corporation  
540 White Plains Road  
P.O. Box 2005  
Tarrytown, NY 10591-9005

**Study Completion Date**

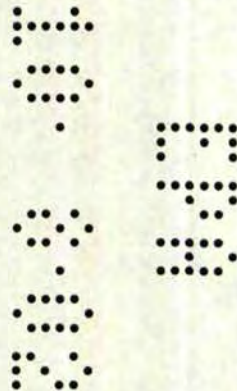
9/13/2002

**Study Number**

B102 Z-WR

**Total Pages**

5

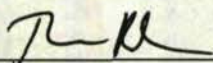




**Statement of Data Confidentiality**

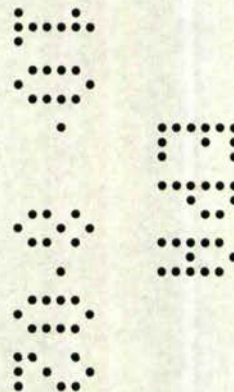
No claim of confidentiality is made for any information contained in this submission on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C).

Company: Ciba Specialty Chemicals Corporation

Signature:   
Thomas Barber

Title: Manager Product Compliance

Date: 9/13/2002

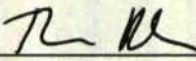




### Good Laboratory Practices Statement

This paper, titled "Irgaguard® B102 Z Request for Waivers" is a discussion and presentation of information. No data are being submitted that are subject to Good Laboratory Practice Standards (40 CFR Part 160).

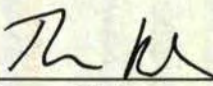
Sponsor:

Signature:   
Thomas Barber

Title: Manager Product Compliance

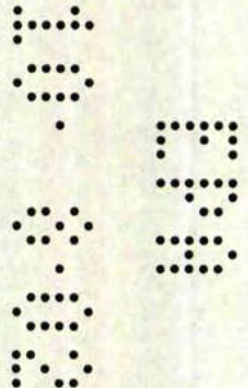
Date: 9/13/2002

Author/Submitter:

Signature:   
Thomas Barber

Title: Manager Product Compliance

Date: 9/13/2002





The purpose of this submission is to request and justify a waiver from submission of data to fulfill certain data requirements which are not applicable to Irgaguard® B102 Z.

**OPPTS 830.6314 Oxidation/Reduction: Chemical Incompatibility**

This data requirement is not applicable to Irgaguard® B102 Z because the product, which is a mixture of inorganic compounds, will not react when placed in contact with oxidizing or reducing agents.

**OPPTS 830.6320 Corrosion Characteristics**

This data requirement is not applicable to Irgaguard® B102 Z because the product, which is a mixture of inorganic compounds, will not react with polyethylene bags in which the product is commercially supplied.

**OPPTS 830.6315 Flammability**

This data requirement is not applicable to Irgaguard® B102 Z because the product is an inorganic solid material, and not a liquid.

**OPPTS 830.6316 Explodability**

The data presented under this MRID applies to a silver-zinc glass antimicrobial of similar nature, consisting of ~6.8% ionically-bound zinc. The explodability potential of the cited MRID product is expected to be identical to Irgaguard B102 Z.

**OPPTS 830.6319 Miscibility**

This data requirement is not applicable to Irgaguard® B102 Z because the product is not an emulsifiable liquid intended for dilution with petroleum solvents.

**OPPTS 830.7100 Viscosity**

This data requirement is not applicable to Irgaguard® B102 Z because the product is not a liquid.

**OPPTS 870.1100 Acute Oral Toxicity – rat**

The data presented under this MRID applies to a silver-zinc glass antimicrobial of similar nature, consisting of ~6.8% ionically-bound zinc. The toxicological profiles of the cited MRID product is expected to be identical to Irgaguard B102 Z.

**OPPTS 870.1200 Acute Dermal Toxicity – rat**

The data presented under this MRID applies to a silver-zinc glass antimicrobial of similar nature, consisting of ~6.8% ionically-bound zinc. The toxicological profiles of the cited MRID product is expected to be identical to Irgaguard B102 Z.



**OPPTS 870.1300 Acute Inhalation Toxicity**

The data presented under this MRID applies to a silver-zinc glass antimicrobial of similar nature, consisting of ~6.8% ionically-bound zinc. The toxicological profiles of the cited MRID product is expected to be identical to Irgaguard B102 Z.

**OPPTS 870.2400 Primary Eye Irritation – rabbit**

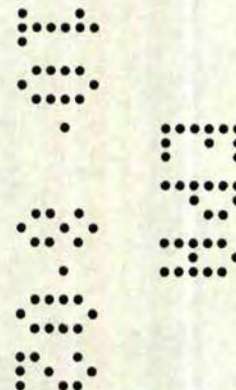
The data presented under this MRID applies to a silver-zinc glass antimicrobial of similar nature, consisting of ~6.8% ionically-bound zinc. The toxicological profiles of the cited MRID product is expected to be identical to Irgaguard B102 Z.

**OPPTS 870.2500 Primary Dermal Irritation**

The data presented under this MRID applies to a silver-zinc glass antimicrobial of similar nature, consisting of ~6.8% ionically-bound zinc. The toxicological profiles of the cited MRID product is expected to be identical to Irgaguard B102 Z.

**OPPTS 870.2600 Dermal Sensitization**

The data presented under this MRID applies to a silver-zinc glass antimicrobial of similar nature, consisting of ~6.8% ionically-bound zinc. The toxicological profiles of the cited MRID product is expected to be identical to Irgaguard B102 Z.





JAN 14 2003

JAN 14 2003

JAN 14 2003

JAN 14 2003

JAN 14 2003

JAN 14 2003

JAN 14 2003

JAN 14 2003

JAN 14 2003





SUBMISSION BAR CODE # 5624957 REVIEWER T KishCODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTSFILE SYMBOL/REG NO. 40810-EL PM 33 ACTION CODE 172DESCRIPTOR Appln For Reg.

[ ] CHILD RESISTANT PACKAGING: [ ] CERTIFICATION  
 [ ] NON-RESIDENTIAL USE ONLY  
 [ ] NOT APPLICABLE

REGISTRATION TYPE: [ ] CONDITIONAL [ ] UNCONDITIONAL

PROPOSED CLASSIFICATION: [ ] GENERAL [ ] RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

09 13 0210 08 0210 10 02

METHOD OF SUPPORT

FORMULATORS EXEMPTION

[ ] CITE ALL  
 [ ] SELECTIVE  
 [ ] NOT SUBMITTED  
 [ ] NOT APPLICABLE  
 [ ] INCORRECT/RESUB

[ ] SUBMITTED  
 [ ] NOT SUBMITTED  
 [ ] NOT APPLICABLE  
 [ ] INCORRECT/RESUB

REVIEW(S) REQUESTED

DATA  
PACK #DATE  
SENTDUE  
DATEDATE  
RETURNED

CHEMISTRY

EFFICACY

TOXICOLOGY

HED TOX.

ENVIRON. FATE

FISH/WILDLIFE

OTHER

STATUS

Needs Revised data matrix

RESPONSE CODE

20

RESPONSE DATE


11/4/02



N/ET

Please read instructions on reverse before completing form

Form Approved, OMB No. 2070-0060, Approval expires 5-31-98

	United States	<input checked="" type="checkbox"/> Registration	OPP Identifier Number  <b>291720</b>
	Environmental Protection Agency	<input type="checkbox"/> Amendment	
	Washington, DC 20460	<input type="checkbox"/> Other	

## Application for Pesticide - Section I

1. Company/Product Number 40810- <u>EL</u>	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Irgaguard® B 102 Z	PM # <u>25 23</u>	
5. Name and Address of Applicant (Include ZIP Code) Ciba Specialty Chemical Corporation 540 White Plains Road P.O. Box 2005 Tarrytown, NY 10591-9005 <input type="checkbox"/> Check if this is a new address	6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg No. <u>40810-17</u> Product Name <u>Irgaguard B8000</u>	

## Section - II

<input type="checkbox"/> Amendment - Explain below	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input checked="" type="checkbox"/> "Me Too" Application
<input type="checkbox"/> Notification - Explain below	<input type="checkbox"/> Other - Explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

## Section III

1. Material This Product Will be Packaged in:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
<b>*Certification must be submitted</b>	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container	<input type="checkbox"/> Plastic
					<input type="checkbox"/> Glass
					<input type="checkbox"/> Paper
					<input checked="" type="checkbox"/> Other (Specify) <u>2 plastic bags (10 kg ea) in a cardboard box</u>
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 2 x 10 kg		5. Location of label directions <input type="checkbox"/> On Label <input checked="" type="checkbox"/> On Label accompanying product	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____			

## Section IV

1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Thomas Barber		Title Manager, Product Compliance	
		Telephone No. (Include Area Code) (914) 785-4311	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law		6. Date Application Received  (Stamped)	
2. Signature 		3. Title Manager, Product Compliance	
4. Typed Name Thomas Barber		5. Date 9/13/2002	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete.

White - EPA File Copy (Original) Yellow - Applicant Copy





United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☐ Other

OPP Identifier Number

291720

## Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name)	PM#	
5. Name and Address of Applicant (Include ZIP Code)  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
* Certification must be submitted				<input type="checkbox"/> Plastic	
If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container	<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name		Title		Telephone No. (Include Area Code)	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature		3. Title			
4. Typed Name		5. Date			



## PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

**PAPERWORK REDUCTION ACT NOTICE:** Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

**INSTRUCTIONS:** This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

**Submission of Labeling** - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

**Submission of Data** - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

**SPECIFIC INSTRUCTIONS:** Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

**Block A** - Check the appropriate action for which you are submitting this form.

**SECTION I** - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

**SECTION II** - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

**SECTION III** (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

**SECTION IV** (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.





United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☐ Other

OPP Identifier Number

29291720

### Application for Pesticide - Section I

1. Company/Product Number <i>FL</i>	2. EPA Product Manager <i>PM# 13</i>	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name)		
5. Name and Address of Applicant (Include ZIP Code)  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

### Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

### Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. _____ No. per container _____	If "Yes" Package wgt. _____ No. per container _____		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

### Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name		Title		Telephone No. (Include Area Code)	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature		3. Title			
4. Typed Name		5. Date			



## PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

**PAPERWORK REDUCTION ACT NOTICE:** Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

**INSTRUCTIONS:** This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

**Submission of Labeling** - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

**Submission of Data** - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

**SPECIFIC INSTRUCTIONS:** Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

**Block A** - Check the appropriate action for which you are submitting this form.

**SECTION I** - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

**SECTION II** - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

**SECTION III** (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

**SECTION IV** (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.



OCT 16 2002

U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs

CIBA SPECIALTY CHEMICALS CORPORATION  
REGULATORY AFFAIRS & LEGAL  
540 WHITE PLAINS ROAD  
TARRYTOWN, NY 10591

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 10/08/02. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



457770-00

Ciba



October 4, 2002

Document Processing Desk (APPL)  
Office of Pesticide Programs (7504C)  
US Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, Virginia 22202-4501

**Attention: Mr. Marshall Swindell (PM33)**

Re: MUP Submission for Irgaguard® B102 Z

40810-EL

Dear Mr. Swindell:

The purpose of this submission is to obtain an manufacturing use product (MUP) registration for Ciba Specialty Chemical's antimicrobial agent, Irgaguard® B102 Z (commercial lab testing identifier TKA 45057), which is substantially similar in chemical composition to Irgaguard® B8000 (EPA Reg. No. 40810-17). Irgaguard® B102 Z is to be used to manufacture other antimicrobial products, which in turn are to be incorporated into polymers and other materials. This is as identified in our meeting with the Agency of October 30, 2001 and the Agency letter of February 5, 2002.

Enclosed with this letter are the following registration materials:

- Application form 8570-1
- Confidential Statement of Formula form 8570-4
- Certification with Respect to Citation of Data form 8570-34
- Data Matrices (Agency & public versions) form 8570-35
- Product label (5 copies)
- Transmittal Document
  - Submitted studies (3 copies each)

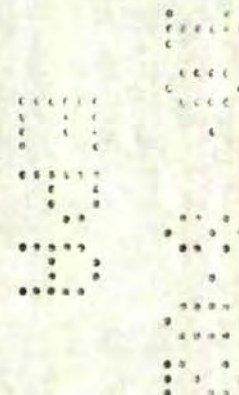
Should you have any questions or wish further information, please do not hesitate to call Tom Barber directly at (914) 785-4311.

Respectfully,

*Naeem H. Mady*  
Naeem Mady  
Head, Regulatory Affairs

540 White Plains Road  
Tarrytown, New York 10591

Tel. 914-785-4311  
Fax 914-785-4147





# TRANSMITTAL DOCUMENT

## Submitter

Ciba Specialty Chemicals Corporation  
540 White Plains Road  
P.O. Box 2005  
Tarrytown, NY 10591-9005

## Regulatory action in support of which this package is submitted

Irgaguard® B102 Z

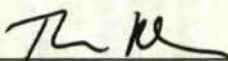
## Transmittal Date

September 13, 2002

## Submitted Studies

	----	Administrative Materials
45777001	Document 1:	Irgaguard® B102 Z - Product Identity, Composition, and Analysis (Group A)
45777002	Document 2:	Irgaguard® B102 Z - Color, Physical State, Odor, pH, and Density
(ADMIN)	Document 3:	Irgaguard® B102 Z - Request for Waivers

Company Official



Company Name:

Ciba Specialty Chemicals Corporation

Company Contact:

Thomas Barber

Phone Number:

(914) 785-4311





**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M STREET, S.W.**  
**WASHINGTON, D.C. 20460**

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.

Do not send the completed form to this address.

**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number Ciba Specialty Chemicals Corporation 540 White Plains Road, PO Box 2005 Tarrytown, NY 10591-9005 (914) 785-4311	EPA Registration Number/File Symbol 40810-
Active Ingredient(s) and/or representative test compound(s) zinc	Date 9/13/2002
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor (material preservative)	Product Name Irgaguard® B 102 Z

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulators Exemption Statement (EPA Form 8570-27)

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT (Check one method only)**

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose)	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
---	---

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method, or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitted to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under applicable law.

Signature 	Date 9/13/2002	Typed or Printed Name and Title Thomas Barber Manager, Product Compliance
---------------	-------------------	---





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

DATA MATRIX

Date:	EPA Reg No./ File Symbol 40810-	Page 1 of 2
Applicant's/Registrant's Name and Address: Ciba Specialty Chemicals Corporation 540 White Plains Road PO Box 2005 Tarrytown, NY 10591-9005	Product: Irgaguard® B102 Z Manufacturing Use	
Ingredient: zinc (PC 129015)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<b>PRODUCT SPECIFIC DATA</b>					
OPPTS 830.1550	Product Identity and Composition		Ciba Specialty Chemicals	Own	
OPPTS 830.1600	Description of Starting Materials		Ciba Specialty Chemicals	Own	
OPPTS 830.1650	Description of the Formulation Process		Ciba Specialty Chemicals	Own	
OPPTS 830.1670	Discussion of the Formation of Impurities		Ciba Specialty Chemicals	Own	
OPPTS 830.1750	Certified Limits		Ciba Specialty Chemicals	Own	
OPPTS 830.1800	Enforcement analytical method		Ciba Specialty Chemicals	Own	
OPPTS 830.6303	Physical state		Ciba Specialty Chemicals	Own	
OPPTS 830.7000	pH		Ciba Specialty Chemicals	Own	
OPPTS 830.6314	Oxidation/reduction: chemical incompatibility		Ciba Specialty Chemicals	Own	See footnote 1
OPPTS 830.6320	Corrosion characteristics		Ciba Specialty Chemicals	Own	See footnote 1
OPPTS 830.6302	Color		Ciba Specialty Chemicals	Own	
OPPTS 830.6304	Odor		Ciba Specialty Chemicals	Own	
OPPTS 830.6315	Flammability		Ciba Specialty Chemicals	Own	See footnote 1
OPPTS 830.6316	Explosibility	45618603	Ciba Specialty Chemicals	Own	See footnote 2
OPPTS 830.6319	Miscibility		Ciba Specialty Chemicals	Own	See footnote 1
OPPTS 830.7100	Viscosity		Ciba Specialty Chemicals	Own	See footnote 1
OPPTS 830.7300	Density		Ciba Specialty Chemicals	Own	
OPPTS 870.1100	Acute oral toxicity – rat	45618604	Ciba Specialty Chemicals	Own	See footnote 2
OPPTS 870.1200	Acute dermal toxicity – rat	45618605	Ciba Specialty Chemicals	Own	See footnote 2
OPPTS 870.1300	Acute inhalation toxicity	45618606	Ciba Specialty Chemicals	Own	See footnote 2
OPPTS 870.2400	Primary eye irritation – rabbit	45618607	Ciba Specialty Chemicals	Own	See footnote 2
OPPTS 870.2500	Primary dermal irritation	45618608	Ciba Specialty Chemicals	Own	See footnote 2
OPPTS 870.2600	Dermal sensitization	45618609	Ciba Specialty Chemicals	Own	See footnote 2

Signature 	Name and Title Thomas Barber Manager Product Compliance	Date 9/13/02
---------------	---	-----------------





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street, S.W.

WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: 9/13/02	EPA Reg No./ File Symbol 40810-	Page 2 of 2
Applicant's/Registrant's Name and Address: Ciba Specialty Chemicals Corporation 540 White Plains Road PO Box 2005 Tarrytown, NY 10591-9005	Product: Irgaguard® B102 Z Manufacturing Use	
Ingredient: zinc (PC 129015)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<b>GENERIC DATA - ZINC</b>					
870.1100	Acute oral toxicity – rat	Waived	Per RED	RED	
870.1200	Acute dermal toxicity – rat	Waived	Per RED	RED	
870.1300	Acute inhalation toxicity	Waived	Per RED	RED	
870.2400	Primary eye irritation – rabbit	Waived	Per RED	RED	
870.2500	Primary dermal irritation	Waived	Per RED	RED	
870.2600	Dermal sensitization	Waived	Per RED	RED	
870.3250	90 day dermal toxicity – rodent	Waived	Per RED	RED	
870.3700	Developmental toxicity – rodent	Waived	Per RED	RED	
870.5265	In vitro mutagenicity	Waived	Per RED	RED	
870.5300	Mutagenicity – mammalian cells in culture	Waived	Per RED	RED	
870.5380	In vivo cytogenetics	Waived	Per RED	RED	
850.1010	Daphnia acute toxicity	42032806 155227	Kanebo Monsanto	Per old	Waived for Most zinc salts in RED
850.1075	Acute toxicity – fish	155224 155228	Monsanto	old	Waived for Most zinc salts in RED
850.2100	Avian Acute toxicity	42870901 155226	Kanebo Monsanto	Per old	Waived for Most zinc salts in RED
835.2120	Hydrolysis	Waived	Per RED	RED	

Footnote 1: Request for Waivers submitted for these tests. Footnote 2: See Request for Waivers for explanation/justification.

Signature 	Name and Title Thomas Barber Manager Product Compliance	Date 9/13/02
---------------	---	-----------------





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 9/13/02	EPA Reg No./ File Symbol 40810-	Page 1 of 2
Applicant's/Registrant's Name and Address: Ciba Specialty Chemicals Corporation 540 White Plains Road PO Box 2005 Tarrytown, NY 10591-9005	Product: Irgaguard® B102 Z Manufacturing Use	
Ingredient: zinc (PC 129015)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
PRODUCT SPECIFIC DATA					
			Ciba Specialty Chemicals	Own	
			Ciba Specialty Chemicals	Own	
			Ciba Specialty Chemicals	Own	
			Ciba Specialty Chemicals	Own	
			Ciba Specialty Chemicals	Own	
			Ciba Specialty Chemicals	Own	
			Ciba Specialty Chemicals	Own	
			Ciba Specialty Chemicals	Own	
			Ciba Specialty Chemicals	Own	See footnote 1
			Ciba Specialty Chemicals	Own	See footnote 1
			Ciba Specialty Chemicals	Own	
			Ciba Specialty Chemicals	Own	
			Ciba Specialty Chemicals	Own	See footnote 1
			Ciba Specialty Chemicals	Own	See footnote 2
			Ciba Specialty Chemicals	Own	See footnote 1
			Ciba Specialty Chemicals	Own	See footnote 1
			Ciba Specialty Chemicals	Own	
			Ciba Specialty Chemicals	Own	See footnote 2
			Ciba Specialty Chemicals	Own	See footnote 2
			Ciba Specialty Chemicals	Own	See footnote 2
			Ciba Specialty Chemicals	Own	See footnote 2
			Ciba Specialty Chemicals	Own	See footnote 2
			Ciba Specialty Chemicals	Own	See footnote 2
			Signature	Name and Title Thomas Barber Manager Product Compliance	





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street, S.W.  
WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: 9/13/02	EPA Reg No./ File Symbol 40810-	Page 2 of 2
Applicant's/Registrant's Name and Address: Ciba Specialty Chemicals Corporation 540 White Plains Road PO Box 2005 Tarrytown, NY 10591-9005	Product: Irgaguard® B102 Z Manufacturing Use	
Ingredient: zinc (PC 129015)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
GENERIC DATA - ZINC					
			Per RED	RED	
			Per RED	RED	
			Per RED	RED	
			Per RED	RED	
			Per RED	RED	
			Per RED	RED	
			Per RED	RED	
			Per RED	RED	
			Per RED	RED	
			Per RED	RED	
			Per RED	RED	
			Per RED	RED	
			Kanebo Monsanto	Per old	Waived for most zinc salts in RED
			Monsanto	old	Waived for most zinc salts in RED
			Kanebo Monsanto	Per old	Waived for most zinc salts in RED
			Per RED	RED	

Footnote 1: Request for Waivers submitted for these tests. Footnote 2: See Request for Waivers for explanation/justification.

Signature 	Name and Title Thomas Barber Manager Product Compliance	Date 9/13/02
---------------	---	-----------------



# IRGAGUARD® B102 Z

Zinc zeolite

An antimicrobial agent for formulating use only.

Active ingredient:

Zinc (as elemental)..... 14.3%

••••• Other ingredients ..... 85.7%

••••• Total ..... 100.0%

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

**FIRST AID:**

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

**IF IN EYES**

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye
- Call a poison control center or doctor for treatment advice

**FOR 24-HOUR EMERGENCY MEDICAL ASSISTANCE, CALL  
1-800-873-1138**

EPA Establishment No. 70404-AL-002

EPA Registration No. 40810-

Net Weight

Lot No.

Ciba Specialty Chemicals Corp.  
Plastic Additives  
540 White Plains Road  
Tarrytown, NY 10591



## PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMANS

**CAUTION.** Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**This product is not approved for any food contact or human drinking water contact uses in the United States.**

Only for formulation into antimicrobial pesticides, for (1) the following uses: the preservation of plastics, fibers, coatings, films, laminates, adhesives, sealants, and other finished products; (2) uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and (3) uses for experimental purposes that are in compliance with USEPA requirements.

### ENVIRONMENTAL HAZARDS

This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

**Pesticide Storage:** Do not store in areas accessible to children. Keep away from direct sunlight.

**Pesticide Disposal:** Wastes from the use of this product may be disposed of on site or at an approved waste disposal facility.

**Container Disposal:** Completely empty bags into processing equipment where the pesticide is used. Then dispose of empty bag and box in sanitary landfill or by incineration, if allowed by state and local authorities.

**IRGAGUARD® is a trademark of Ciba Specialty Chemicals Corporation**

EPA Approval Date: NOT EPA APPROVED. Draft 9-13-2002



# IRGAGUARD® B102 Z

Zinc zeolite

An antimicrobial agent for formulating use only.

Active ingredient:

Zinc (as elemental)..... 14.3%

Other ingredients ..... 85.7%

Total ..... 100.0%

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

**FIRST AID:**

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

**IF IN EYES**

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye
- Call a poison control center or doctor for treatment advice

**FOR 24-HOUR EMERGENCY MEDICAL ASSISTANCE, CALL  
1-800-873-1138**

EPA Establishment No. 70404-AL-002

EPA Registration No. 40810-

Net Weight

Lot No.

Ciba Specialty Chemicals Corp.  
Plastic Additives  
540 White Plains Road  
Tarrytown, NY 10591



## **PRECAUTIONARY STATEMENTS**

### **HAZARDS TO HUMANS**

**CAUTION.** Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

### **DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**This product is not approved for any food contact or human drinking water contact uses in the United States.**

Only for formulation into antimicrobial pesticides, for (1) the following uses: the preservation of plastics, fibers, coatings, films, laminates, adhesives, sealants, and other finished products; (2) uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and (3) uses for experimental purposes that are in compliance with USEPA requirements.

### **ENVIRONMENTAL HAZARDS**

This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

### **STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage and disposal.

**Pesticide Storage:** Do not store in areas accessible to children. Keep away from direct sunlight.

**Pesticide Disposal:** Wastes from the use of this product may be disposed of on site or at an approved waste disposal facility.

**Container Disposal:** Completely empty bags into processing equipment where the pesticide is used. Then dispose of empty bag and box in sanitary landfill or by incineration, if allowed by state and local authorities.

**IRGAGUARD® is a trademark of Ciba Specialty Chemicals Corporation**

EPA Approval Date: NOT EPA APPROVED. Draft 9-13-2002



# IRGAGUARD® B102 Z

Zinc zeolite

An antimicrobial agent for formulating use only.

Active ingredient:

Zinc (as elemental) .....	14.3%
Other ingredients .....	85.7%
Total .....	100.0%

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

**FIRST AID:**

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

**IF IN EYES**

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye
- Call a poison control center or doctor for treatment advice

**FOR 24-HOUR EMERGENCY MEDICAL ASSISTANCE, CALL  
1-800-873-1138**

EPA Establishment No. 70404-AL-002

EPA Registration No. 40810-

Net Weight

Lot No.

Ciba Specialty Chemicals Corp.  
Plastic Additives  
540 White Plains Road  
Tarrytown, NY 10591



## PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMANS

**CAUTION.** Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

This product is not approved for any food contact or human drinking water contact uses in the United States.

Only for formulation into antimicrobial pesticides, for (1) the following uses: the preservation of plastics, fibers, coatings, films, laminates, adhesives, sealants, and other finished products; (2) uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and (3) uses for experimental purposes that are in compliance with USEPA requirements.

### ENVIRONMENTAL HAZARDS

This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

**Pesticide Storage:** Do not store in areas accessible to children. Keep away from direct sunlight.

**Pesticide Disposal:** Wastes from the use of this product may be disposed of on site or at an approved waste disposal facility.

**Container Disposal:** Completely empty bags into processing equipment where the pesticide is used. Then dispose of empty bag and box in sanitary landfill or by incineration, if allowed by state and local authorities.

IRGAGUARD® is a trademark of Ciba Specialty Chemicals Corporation

EPA Approval Date: NOT EPA APPROVED. Draft 9-13-2002



# IRGAGUARD® B102 Z

Zinc zeolite

An antimicrobial agent for formulating use only.

Active ingredient:

Zinc (as elemental)..... 14.3%

Other ingredients ..... 85.7%

Total ..... 100.0%

**KEEP OUT OF REACH OF CHILDREN**

## CAUTION

### FIRST AID:

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

#### IF IN EYES

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye
- Call a poison control center or doctor for treatment advice

**FOR 24-HOUR EMERGENCY MEDICAL ASSISTANCE, CALL  
1-800-873-1138**

EPA Establishment No. 70404-AL-002

EPA Registration No. 40810-

Net Weight

Lot No.

Ciba Specialty Chemicals Corp.  
Plastic Additives  
540 White Plains Road  
Tarrytown, NY 10591



## **PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS**

**CAUTION.** Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

## **DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**This product is not approved for any food contact or human drinking water contact uses in the United States.**

Only for formulation into antimicrobial pesticides, for (1) the following uses: the preservation of plastics, fibers, coatings, films, laminates, adhesives, sealants, and other finished products; (2) uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and (3) uses for experimental purposes that are in compliance with USEPA requirements.

## **ENVIRONMENTAL HAZARDS**

This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

## **STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage and disposal.

**Pesticide Storage:** Do not store in areas accessible to children. Keep away from direct sunlight.

**Pesticide Disposal:** Wastes from the use of this product may be disposed of on site or at an approved waste disposal facility.

**Container Disposal:** Completely empty bags into processing equipment where the pesticide is used. Then dispose of empty bag and box in sanitary landfill or by incineration, if allowed by state and local authorities.

**IRGAGUARD® is a trademark of Ciba Specialty Chemicals Corporation**

EPA Approval Date: NOT EPA APPROVED. Draft 9-13-2002



# IRGAGUARD® B102 Z

Zinc zeolite

An antimicrobial agent for formulating use only.

Active ingredient:

Zinc (as elemental).....	14.3%
Other ingredients .....	85.7%
Total .....	100.0%

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

**FIRST AID:**

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

**IF IN EYES**

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye
- Call a poison control center or doctor for treatment advice

**FOR 24-HOUR EMERGENCY MEDICAL ASSISTANCE, CALL  
1-800-873-1138**

EPA Establishment No. 70404-AL-002

EPA Registration No. 40810-

Net Weight

Lot No.

Ciba Specialty Chemicals Corp.  
Plastic Additives  
540 White Plains Road  
Tarrytown, NY 10591



## **PRECAUTIONARY STATEMENTS**

### **HAZARDS TO HUMANS**

**CAUTION.** Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

### **DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**This product is not approved for any food contact or human drinking water contact uses in the United States.**

Only for formulation into antimicrobial pesticides, for (1) the following uses: the preservation of plastics, fibers, coatings, films, laminates, adhesives, sealants, and other finished products; (2) uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and (3) uses for experimental purposes that are in compliance with USEPA requirements.

### **ENVIRONMENTAL HAZARDS**

This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

### **STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage and disposal.

**Pesticide Storage:** Do not store in areas accessible to children. Keep away from direct sunlight.

**Pesticide Disposal:** Wastes from the use of this product may be disposed of on site or at an approved waste disposal facility.

**Container Disposal:** Completely empty bags into processing equipment where the pesticide is used. Then dispose of empty bag and box in sanitary landfill or by incineration, if allowed by state and local authorities.

**IRGAGUARD® is a trademark of Ciba Specialty Chemicals Corporation**

EPA Approval Date: NOT EPA APPROVED. Draft 9-13-2002





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

10/10/2002

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

CIBA SPECIALTY CHEMICAL CORPORATION  
540 WHITE PLAINS ROAD  
P. O. BOX 2005  
TARRYTOWN, NY 10591-9005

PRODUCT NAME: IRGAGUARD® B 102 Z  
COMPANY NAME: CIBA SPECIALTY CHEMICAL CORPORATION  
OPP IDENTIFICATION NUMBER: 291720  
EPA FILE SYMBOL: 40810-EL  
EPA RECEIPT DATE: 10/08/02

SUBJECT: RECEIPT OF APPLICATION FOR A NEW REGISTRATION

DEAR REGISTRANT:

The Office of Pesticides Programs has received your application for a new registration and it has passed an administrative screen for completeness.

Please note that this is only a notification of receipt of your application. This is only the first step in the application process, and does NOT constitute approval.

If you have any questions, please contact Joanne Miller at 703-305-6224.

Sincerely,

A handwritten signature in cursive script that reads "Patricia A. Moore".

Front End Processing Staff  
Information Services Branch  
Information Resources & Services Division



